

**School of Physiotherapy**

**Exploring different models of stroke unit care and outcome:  
The Stroke Rehabilitation Outcome (SRO) study**

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**This thesis is presented for the Degree of  
Doctor of Philosophy  
of  
Curtin University of Technology**

**January 2013**



## **DECLARATION**

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

Diane Dennis

January 2013



## **ABSTRACT**

### **Introduction:**

Stroke is a significant cardiovascular event requiring sub-acute rehabilitation, best provided in a stroke unit (SU). These units include dedicated neurological SUs usually catering only for patients with stroke and more generic SUs existing within geriatric rehabilitation units (GRUs). There exists a “grey” group of survivors of stroke whose allocation to one type of rehabilitation facility over another is arbitrary, in that the referring physician had no evidence to suggest advantages of SU versus GRU rehabilitation.

### **Objectives:**

The aim of this inception cohort study was to provide a direct comparison of quality of life and functional outcome between two commonly applied models of organised multidisciplinary SU rehabilitation for the “grey” group of stroke survivors. Further, it evaluated differences in the intensity of treatment and the environment in which rehabilitation was implemented.

### **Method:**

All patients presenting to Royal Perth Hospital-Wellington Street Campus acute stroke unit (RPH-WSC ASU) with a diagnosis of recent stroke requiring hospitalisation and subacute rehabilitation were considered for inclusion into the study. Patients were selected based on their age, absence of dementia and their acceptance by incumbent medical staff for rehabilitation transfer at either Royal Perth Hospital-Shenton Park Campus stroke unit (SPC SU) or at a GRU geographically closest to their home (located at either Mercy hospital, Bentley hospital or Swan health campus).

Baseline data was collected in order to establish the underlying level of disability and compare groups for comparability, and also to be used as covariates in data analysis.

All treatments received were those considered standard for the individual facility, administered as usual by registered health professionals. During the study, periodic behaviour mapping at each of the study facilities was undertaken by a research assistant in order to quantify differences in the rehabilitation environment. In addition, attending therapists at each facility recorded the frequency and duration of their intervention with individual patients involved in the study in a patient diary designed for that purpose. Six and twelve months following their transfer from RPH-WSC ASU, patients attended follow-up outpatient appointments at neutral rooms where objective and subjective assessments were undertaken by an independent assessor (a physiotherapist) who was blinded as to which rehabilitation facility the patient had attended. The primary outcome measure was the MOS 36-Item Short Form Health Survey (SF-36) and secondary outcome measures included the Functional Independence Measure (FIM) and other functional measures.

#### Results:

Between July 2004 and June 2007, 354 patients with stroke were age appropriate (60 years of age or older) for recruitment into the study and of these, 94 consented to participate (SPC SU n=22; GRUs n=72). Patients referred to SPC SU were younger, more likely to be male, and have speech abnormality, peripheral vascular disease and diabetes than those referred to GRUs. Otherwise there were no significant differences between groups in any of the characteristics measured at baseline. Rehabilitation data demonstrated a significant difference in both the total allied health professional (AHP) therapy time ( $p<0.001$ ) and the indirect support time such as telephone calls and meetings with family ( $p=0.022$ ), with SPC SU therapists utilising more time compared with GRU therapists. There was no significant difference in time spent undertaking administration including writing notes and reports ( $p=0.957$ ). Data showed significant difference in length of stay (LOS), whereby patients spent a longer time at SPC SU ( $p=0.036$ ), however there was no significant difference in discharge destination between facilities ( $p=0.312$ ). Of the 10 unadjusted patient measures in this study, there were significant differences

between groups in only two, the Berg balance score and the Chedoke McMaster posture inventory. The differences in both of these secondary outcomes favoured the SPC SU group. In addition there were differences in the SF36 Mental component summary (MCS) and Physical component summary (PCS) scores that approached significance. The difference in the PCS scores also favoured the SPC SU group but for the MCS score it was the GRU group that had more favourable scores.

As the study was not randomized, age and gender, which differed between groups at baseline, and Barthel Index score, known to be associated with length of stay in stroke patients, were added to the models as covariates. As data from 6 and 12 month follow-ups was included in the dependent variable, “visit” was added to the models. After these adjustments there were no significant differences between facilities in any quality of life or functional outcomes.

#### Discussion:

Overall there was relatively high quality of life, and low anxiety and depression reported and results were not influenced by where rehabilitation took place. Selection criteria excluding dementia and young age may in part explain this, as both have been found to predict worse quality of life outcome in stroke. Significant differences in both where patients were, and what they were doing throughout the day reflected different ethos between facilities in the way rehabilitation was delivered. However, there was no difference in functional outcome despite these environmental differences and the fact that patients experienced more intensive treatment over a more prolonged hospital stay at SPC SU.

#### Conclusion:

In most cases, rehabilitation of this “grey” subgroup of the wider population of stroke may be more cost-effective if carried out at GRUs (with higher patient/ staff ratios, less intensive treatment and shorter LOS) rather than the neurological SUs.

## **ACKNOWLEDGEMENTS**

Heartfelt thanks to the patients with Stroke who willingly agreed to participate in the project in spite of the sudden onset of their illness and the functional impairment experienced. Obviously there would have been no study without your involvement, and hopefully your participation will have helped others in the future. Also a big thank you to the patient carers who agreed to facilitate outpatient assessments by providing transport to appointments despite the often significant impact of the patient's illness on their own lives.

To all of the medical and allied health professionals who cooperated with the implementation of the study protocol at all sites, and especially those involved in the collection of data, and those who agreed to be observed during behaviour mapping, a huge thanks. Particular thanks to physiotherapists Jacquie Ancliffe and the team at RPH-WSC as well as Karen Smith at SPC SU for their incredible patience and wonderful feedback before, during and after data was collected. Your dedication to stroke rehabilitation is something we all aspire to.

Thank you for the monumental efforts of my supervisor and mentor, Dr Kathy Briffa, who has been extraordinarily intelligent, energetic, encouraging, patient, and inspirational over such a prolonged period. In addition to her overall supervision of my work, her input was fundamentally important in the successful National Heart Foundation grant application. Her continued faith in my ability to actually complete the study and her resourcefulness in helping me to do so has continued to the very end, and I will be forever grateful. Kathy was a great friend long before she was a supervisor, and I wouldn't and couldn't have done this without her.

To Professor's Graeme Hankey and Leon Flicker I extend a special acknowledgment. Graeme suggested the project in the first place so many years ago, and agreed to help, design and instigate the study on his stroke unit at RPH-WSC. Since then, both he and Leon have been a great source of information and advice in



helping to get the project through the various Ethics committees, acquire a grant-in-aid from the National Heart Foundation and provide informed positive feedback on everything from the study design, to the implementation and interpretation of results. Their co-operation has essentially ensured and enabled the project to be successful and I am hugely indebted to them both.

I would also like to acknowledge the generous assistance of Jeff Ewen to design and adapt the study database, and extract data when needed. Also for all those late night phone calls demanding immediate IT help when various computers unexplainably swallowed data or text. Thanks Jeff, for always being ridiculously accessible and willing to help – I'm sure you are equally as excited as I am to have this completed!

To physiotherapists Jo Bouckley and Louise Wise, a huge thankyou. Cheerfully reliable Jo managed to coordinate patient recruitment and outpatient appointments whilst juggling her own final years of university study; Louise, with young children of her own, managed to complete follow-up assessments at 6 and 12 months over 2 years. Her warm, thorough and professional approach to everything she does made my life very easy. Also thanks to Gill Vinton for diligently collecting the behaviour mapping data during that time.

To my physiotherapist-now-medical-doctor friend, Rose Wyllie, I am extremely grateful for help in setting up the behaviour mapping component of the study. It's nice to surround yourself with friends when you undertake a huge project such as this, and Rose is one of those people who have remained encouraging and excited at the little things over a long period of time.

I would also like to acknowledge Dr Anne Smith for her expert and timely statistical advice and analyses, and her guidance in the interpretation of all things statistical. I would also like to thank Dr Richard Parsons for his early work on statistical data.

Thanks to Dr Sophie Coleman for her editing, formatting and overall organization of my thesis; and to Professor Joan Cole for her help in proofreading early versions and providing insightful comments and feedback.

I would also like to acknowledge my work colleagues at the Sir Charles Gairdner Hospital in Perth, Western Australia whom I regard as some of my closest friends. Particularly Tracy Hedben-Todd, Ian Cooper and Wendy Jacob, who have afforded me the time to finish the writing up of my thesis and who have always been a huge source of encouragement and support. It is a privilege to work with such caring, friendly and professional individuals.

I also gratefully acknowledge the financial assistance provided by the grant-in-aid from the National Heart Foundation. There is no doubt in my mind that the study would have not been completed were it not for this support.

Finally, a very special mention of my closest support and inspiration, my lovely husband Jeff and our beautiful children Madeleine, Dimity and Grayson. This study and all it involves has been a part of this family for a very long time, as we carried it with us to Sydney and then to Canada and back to Perth again. It is exciting to have it finally completed and to move forward toward the next chapter of our lives. I wish to also thank my wonderful parents Maria and Fred Acott for their love and encouragement and not least of all, their babysitting. And so now, what next?

## **ABBREVIATIONS**

|          |  |
|----------|--|
| ADL      | activities of daily living                                 |
| AHP(s)   | Allied health professional(s)                              |
| ARAT     | Action Research Arm Test                                   |
| ASU      | acute stroke unit  |
| Bentley  | Bentley health service                                     |
| BBS      | Berg Balance Scale   |
| BI       | Barthel Index  |
| CT       | Computer Tomography  |
| EQ5D VAS | European Quality of Life-5 Dimension Visual Analogue Scale |
| FIM      | Functional Independence Measure                            |
| FH       | Fremantle Hospital   |
| FTE      | full time equivalency                                      |
| GRU(s)   | geriatric rehabilitation unit(s)                           |
| GW       | general ward   |
| HADS     | Hospital Anxiety and Depression Scale                      |
| LAC      | lacunar infarction   |
| LOS      | length of stay   |
| Mercy    | Mercy hospital   |
| MCS      | Mental Component Summary score of the SF36 measure         |
| MMSE     | Mini-mental State Examination                              |
| MRI      | Magnetic Resonance Imaging                                 |
| PAC      | partial anterior circulation infarction                    |
| PCS      | Physical Component Summary score of the SF36 measure       |
| POC      | posterior circulation infarction                           |
| PVD      | peripheral vascular disease                                |
| Rankin   | Rankin score   |
| RCT      | Randomized controlled trial                                |
| RPH-WSC  | Royal Perth Hospital-Wellington Street Campus              |

|        |  |
|--------|--|
| SCGH   | Sir Charles Gairdner Hospital            |
| SF36   | MOS 36-Item Short Form Health Survey     |
| SPC SU | Royal Perth Hospital-Shenton Park Campus |
| SRO    | Stroke Rehabilitation Outcome            |
| SSS    | Scandinavian Stroke score                |
| Swan   | Swan health service                      |
| SU     | stroke unit                              |
| TAC    | total anterior circulation infarction    |
| tPA    | tissue plasminogen activator             |
| VAS    | visual analogue scale                    |
| WHO    | World Health Organization                |

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# CHAPTER 1

## INTRODUCTION

### 1.1 Overview of Stroke

A diagnosis of “stroke” may be made in the presence of rapidly developing symptoms or signs of focal or global loss of cerebral function lasting more than 24 hours or leading to death (Bamford, Sandercock et al. 1991). Stroke is a major public health problem in Australia, as it is throughout the world (Hankey 1999) with more than 40,000 Australians being affected by stroke every year (Hankey, Jamrozik et al. 2000; Thrift, Dewey et al. 2000). In 2006 stroke became Australia’s second biggest killer after coronary heart disease (Australian Institute of Health and Welfare 1996-1997). Among the 28,000 survivors of stroke each year, at least 12,000 remain permanently disabled, and dependent on carers to help them with regular activities of daily living (Hankey, Jamrozik et al. 2002).

The consequences of stroke to the individual, their carer(s) and the community are significant in terms of disability, burden on carers, use of medical and community resources, productivity losses and personal financial costs. The estimated total lifetime costs for stroke in 1997 was A\$1.3 billion (Dewey, Thrift et al. 2003). Two complementary strategies to reduce the burden of stroke on the individual, their carers, and the community are prevention of a first-ever and recurrent stroke, and effective treatment of survivors of stroke.

### 1.2 Management of Stroke

Medical and nursing staff are responsible for the initial stability of the primary medical condition of patients with stroke. This includes the prevention and/or minimization of secondary effects and this care may be overseen by a number of medical clinical specialities in the acute setting.

In sub-acute recovery, a complex package of rehabilitation is the most frequently applied treatment modality to improve the quality of life (Kwakkel, Wagenaar et al. 1999, Pomeroy, 2000). The members of the team depend on the patient's physical, cognitive and emotional disorders, as well as the availability of rehabilitation resources. Physiotherapists, occupational therapists and speech pathologists provide therapy programs according to the resources available and the individual preference to different treatment concepts and philosophies, and optimal functional recovery is the ultimate goal (Kwakkel, Wagenaar et al. 1999).

Rehabilitation outcome for patients with stroke has been shown to be superior in dedicated stroke units (SU) (Aborderin 1996) and at least two different types of SUs have been identified (Langhorne and Pollock 2002). There are dedicated neurological stroke units providing care for only patients with neurological disabilities, and more generic stroke units within geriatric facilities (GRUs). Both types of SUs have been associated with better outcomes for patients with stroke than care in a general medical ward (Stroke Unit Trialist's Collaboration 1997).

### 1.3 Current practice in stroke rehabilitation, Perth, Western Australia

Following acute care at the Royal Perth Hospital, Wellington Street Campus (RPH-WSC), patients may be transferred to either the SU at the Royal Perth Hospital, Shenton Park Campus (SPC SU) or to a GRU in another hospital.

In general, the SPC SU aims to facilitate recovery of normal function, and initially withhold physical aids. This approach may require longer length of inpatient stay in order for patients to achieve independence. The GRUs may be more likely to accept adaptation to functional impairment and disability enabling earlier discharge home, albeit with less than normal movement. This may potentate social benefits such as less isolation and faster return to their familiar environment.

Consequently, younger patients (some with an excellent potential for full recovery) have been routinely transferred to SPC SU for high intensity rehabilitation. Older patients who have more co-morbidities and perhaps less capacity to cope with an intensive rehabilitation program have been transferred to a local GRUs where they may be closer to their own social support network.

There remains a mid-aged group of stroke patients with both the potential to return to some form of independent living as well as the ability to cope with intensive rehabilitation. Historically in this group, allocation to one type of rehabilitative facility over another has been arbitrary, in that the attending physician had no objective evidence to suggest advantages of one model or other.

#### 1.4 Aim and hypothesis

The aim of this inception cohort study was to provide a direct comparison of functional outcome between two commonly applied models of organised multidisciplinary SU rehabilitation for survivors of stroke whose allocation to one type of rehabilitative facility over another was arbitrary. Further, it evaluated differences in the intensity of treatment and the environment in which rehabilitation was implemented.

The independent variable for this study was the type of facility where the rehabilitation was undertaken (SPC SU versus GRU), and the null hypothesis was that both types of facilities were equivalent. The primary outcome variable was the MOS 36-Item Short Form Health Survey (SF36) score. Equivalence was also assessed by secondary variables that addressed function, anxiety and depression, resource utilization, treatment environment and discharge destination.

## 1.5 Study timeframe

This study was first conceived in 2001. Review of the literature involving stroke and stroke rehabilitation was undertaken in order to design and develop this research protocol (Chapter 2). In the period between conception and conclusion of the study, literature was periodically updated in order to identify changes in stroke management. This has resulted in the final thesis reporting the most up to date trends of the incidence and distribution of stroke, as well as the progressive changes leading to the current medical management of acute stroke, including thrombolysis. The need for rehabilitation and the preference for stroke unit management has remained unchanged during this time. Pilot data were collected regarding sample size and feasibility of the trial during 2001 and 2002. Further pilot work was undertaken in 2001 and 2004 in order to both test some perceptions held by various health professionals about the facilities, and develop tools for use in the final trial (Chapter 3). The selection of outcome measures was undertaken in collaboration with expert clinicians within the specialties of neurology and geriatrics, and was in keeping with published data related to the reliability and specificity of the measures for use in research relating to stroke (Chapter 4). Both historical papers (where measures were first published) and those published more recently (where tools were validated for use in the cohort of patients with stroke) have been cited, the latter of which were identified during annual literature updates during the implementation and write up of the study. Initial methodology was trialled in 2003 and 2004 and the final study commenced in June 2004 with the recruitment of the first patient (Chapter 5). First six month follow-ups were completed in December 2004. Patient recruitment was completed at the end of November 2006. Final twelve-month follow-ups were completed in November 2007 (Chapters 6, and 7). Final conclusions are detailed in Chapter 8, followed by Appendices.

Addendum:

There has been some time between follow up final data collection and the write up of this thesis. Anecdotally, on discussion with key staff at each study site, during this time there has been little change in

- the referral pattern of patients with stroke from RPH-WSC
- the criteria for acceptance of patients with stroke for rehabilitation at RPH-SPC SU
- the geographical layout of each study site (RPH-SPC SU or the GRUs)
- the overall implementation of rehabilitation at each study site (RPH-SPC SU or the GRUs)
- the staffing levels at each study site (RPH-SPC SU or the GRUs)

Consequently, there is no reason to believe that the conclusions drawn are not as reasonable or as relevant today as they were when final data collection was completed in 2007.

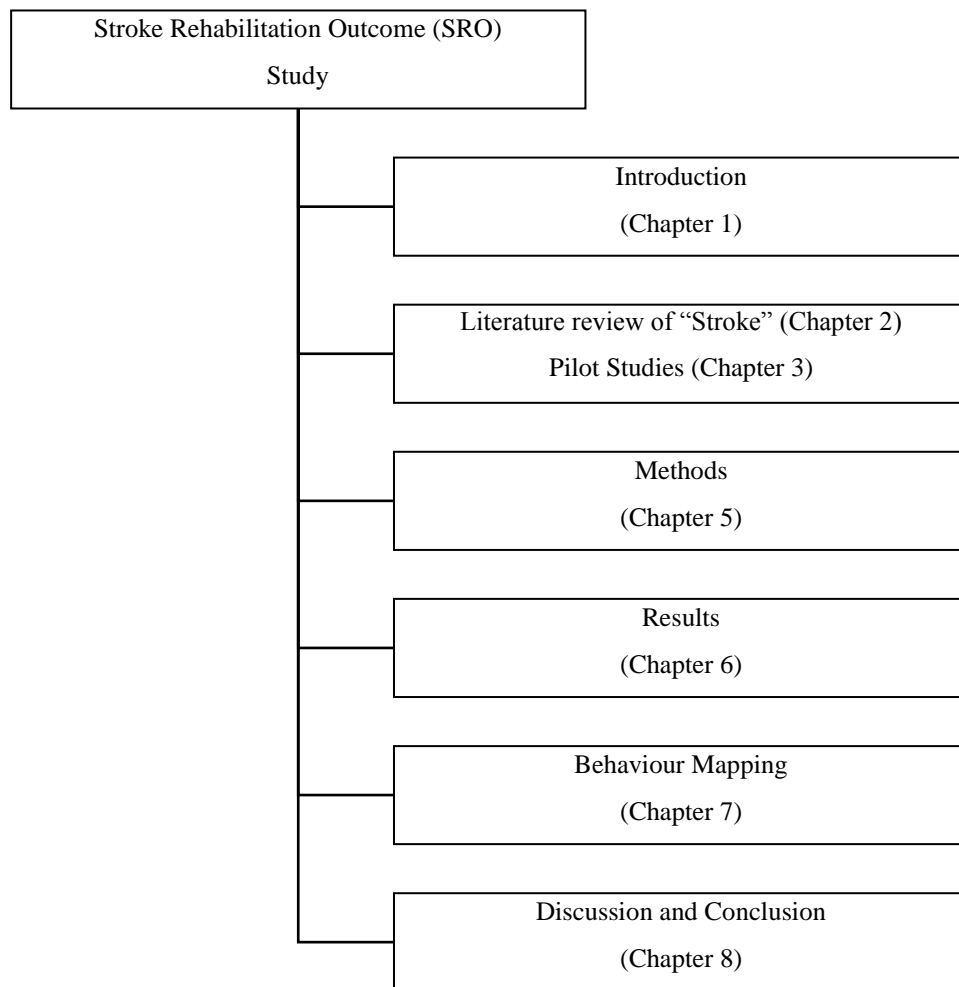


Figure 1.5.1 Chapter Flow Chart



## CHAPTER 2

### STROKE

#### 2.1 Definition of Stroke

In normal healthy humans, blood is carried through the brain by arteries and veins, thereby supplying both oxygen and nutrients to sustain brain tissue and function. When this blood supply is interrupted either by a blockage to the blood vessel (causing lack of blood) or by a burst blood vessel (causing a bleed within the brain) brain cells may be damaged or may die. The medical term for this condition is known as a “cerebrovascular accident” or “stroke”. The word stroke was first used as a synonym for the Greek word, apoplexy, which means to be struck down, as in a seizure (Nilsen 2010).

Strokes may be ischaemic or haemorrhagic. Ischaemic strokes are most commonly caused by a blood clot, whereas bleeds are commonly caused by long standing high blood pressure and disorders where there are weaknesses in the blood vessel wall, like aneurysms. It is important to distinguish between the type of stroke because the treatment of each is quite different. The Perth Community Stroke Study (Islam, Anderson et al. 2008) of 183 first-ever stroke patients in 2001 found 75.4% of strokes were ischaemic, and this is consistent with world-wide data (Hisham and Bayraktutan 2012).

Stroke may cause brain cell damage resulting in permanent impairment in function, or untreated, may result in death. The anatomical location of the stroke is important because different areas of the brain are responsible for different functions, including breathing and heartbeat, movement, sensation, language, swallowing and cognition. Although two people sustaining a stroke in the same location may be affected differently, there are similarities between strokes occurring in the same location. A

stroke located deep within the brain may affect the vital functions of breathing and heartbeat. A stroke on the right side of the brain generally causes problems on the left side of the body, and a stroke on the left side of the brain causes problems on the right side of the body. The Oxfordshire Community Stroke Project (Lindley, Warlow et al. 1993) defined a clinical classification of stroke subtypes that has been adopted by many centres in everyday clinical and research practice and in order to predict early mortality and functional outcome. This classification comprises total anterior circulation infarction (TAC), partial anterior circulation infarction (PAC), lacunar infarction (LAC), and posterior circulation infarction (POC). The most common stroke subtype is the PAC (Hallström, Jönsson et al. 2008), and it is generally accepted that the TAC subtype has the worst outcome in terms of mortality and morbidity (Stone, Alder et al. 2000).

The timing of the event is also important. Brain cells may die quickly, but with collateral supply, sometimes they may last for a few hours. How much brain tissue is permanently damaged may depend upon early medical intervention. Death may occur early as a result of pressure on vital breathing centres or it may occur later as a result of secondary complications such as pneumonia brought about by poor airway protection from cranial nerve damage (<http://strokefoundation.com.au>).

## 2.2 Extent of Stroke world-wide, and in Australia

### 2.2.1 Incidence

According to the World Health Organization, cardiovascular diseases are the leading cause of death in the world (WHO 2004). Acute cardiovascular events include both myocardial infarction and stroke, and the incidence of stroke currently exceeds the incidence of coronary heart disease (Rothwell, Coull et al. 2005). Although there has been a decline in incidence of stroke on the western side of Australia between 1989 and 2001 (Islam, Anderson et al. 2008) and this trend has been reported elsewhere in high-income countries (Feigin, Lawes et al. 2009), it remains a major public health problem in Australia, as it is throughout the world. Risk factors include hypertension

and current smoking (O'Donnell, Xavier et al. 2010; Phillips, Leyden et al. 2011; von Sarnowski, Putaala et al. 2012).

### 2.2.2 Age and gender distribution

In terms of sex differences, a worldwide review of 98 articles reporting stroke epidemiology concluded that the mean age of first-ever stroke in North America and Australasia was 68.6/73.3 years (male/female) and stroke was more common in men (33% higher incidence rate than women) (Appelros, Stegmayr et al. 2009). Other studies have suggested that women are more globally older than men at stroke onset (Xiao-ying Yao 2012). The Perth Community Stroke Study reported a slightly higher overall median age of stroke onset of 77 years (range 32-98) and almost equal gender distribution (% males/females: 48.1/51.9) (Islam, Anderson et al. 2008).

### 2.2.3 Socioeconomic and racial distribution

Recent data from the United States of America has suggested that community poverty is associated with worse stroke severity and that socioeconomic status may impact stroke severity via medication compliance, access to care, and cultural factors (Kleindorfer, Lindsell et al. 2012). There is also evidence for an influence of socioeconomic status and racial disparity in the United States in the treatment of stroke, whereby African Americans, Hispanics, and low median income patients are less likely to receive thrombolysis for ischemic stroke, and low median income patients are less likely to be treated at high-volume hospitals (Kimball, Neal et al. 2012). Like Australian data is unavailable but Western Australian data relating to the disparities in health status between Aboriginal and Torres Strait Islander peoples and the total Australian population has suggested that stroke contributes to 3% of the indigenous health gap in Australia (Vos, Barker et al. 2009).

## 2.3 Acute care management

Although the management of acute stroke advanced considerably with the advent of Computer Tomography (CT) head scanning in the late 1970s, when this tool became the first choice and primary diagnostic test in the diagnosis of stroke (Azar Kia 1977; Davis 1977; Walshe 1977), basic resuscitation has remained the same for some years. Medical personnel of various clinical specialties are responsible for patients' initial stability in terms of resuscitation (providing patent airway, breathing support and blood circulation pressure and volume) and this may include the prevention and/or minimization of secondary effects, such as pneumonia.

### 2.3.1 Diagnosis

As suggested previously, establishing the type of stroke is very important in the early management of the patient, as the treatment of each is quite different. A CT scan will be undertaken at most facilities to determine the location, extent and type of stroke. In addition, since the early 1990's, a Magnetic Resonance Imaging (MRI) scan may be also be available in some major centres. It is generally accepted that CT should occur for all stroke patients as soon as possible after a stroke (Wardlaw, Lewis et al. 1999). Blood tests are also undertaken to check the clotting ability of blood, and other blood chemistry levels (for example, iron which can influence oxygenation of brain cells and potassium which can alter heart rhythms). If the stroke is found to be ischaemic, there may also be tests done relating to cardiac function, as abnormal rhythms and heart valve dysfunction can cause abnormal blood clotting. A neck ultrasound or carotid angiogram may also be undertaken to look for clots or narrowing of blood vessels that may have contributed to the initial stroke, or that may contribute to further deterioration.

### 2.3.2 Management

A landmark study in 2006 quantified the rate of neuronal loss in an untreated stroke patient at 1.9 million neurons per minute (Saver 2006), and this has demonstrated that definitive timely treatment of stroke is of the utmost importance.

If a clot causes the stroke there are two definitive therapies, one to remove the clot (thrombectomy) and one to break the clot down (thrombolysis). Thrombectomy involves the insertion of a catheter into the femoral artery, directing it into the cerebral circulation, ensnaring the clot, and withdrawing it. This technique has become increasingly popular with advances in interventional medical imaging (Berlis, Lutsep et al. 2004; Smith, Sung et al. 2005; Smith 2006). Thrombolysis involves the administration of a drug (usually tissue plasminogen activator (tPA) that breaks the clot down, but this therapy must begin within 4.5 hours of the stroke to be effective (Davis and Donnan 2009). Other drugs aimed at preventing new clots forming or clot enlargement may also be administered. These include aspirin, clopidogrel and dipyridamole.

If the stroke has been caused by a bleed, the cause of the bleed needs to be detected (utilising investigations such as cerebral angiogram), and may require medical management (in the case of high blood pressure) or neurosurgical management (in the case of burst blood vessel wall). Removal of the bleed itself may also be indicated if it is causing pressure on the brain that may cause secondary damage.

### 2.3.3 Acute Stroke Units

Care of a patient with acute stroke may be undertaken in a number of different settings within departments of general medicine, neurology or geriatric medicine, where patients may be managed alongside a range of other patient groups. The term 'Stroke Unit' (SU) has been used to describe organised inpatient care occurring at a geographically distinct location or in a specialised facility housing a specialist coordinated team dealing exclusively with patients diagnosed with stroke (Stroke

Unit Trialist's Collaboration 1997).. The arguments for and against the acute stroke unit (ASU) concept have been debated in the literature since the late 1980s, but repeated systematic reviews (Stroke Unit Trialist's Collaboration 1997; Stroke Unit Trialists' Collaboration 2007) and independent studies (Hankey and Warlow 1999) have demonstrated that compared with conventional generic care, treatment of stroke in a designated ASU decreases the odds of death, institutionalization and dependency levels compared to treatment in a general ward (GW).

A Norwegian study first identified the differences between ASU and GW treatment programs, evaluating the care of 206 acute stroke patients (Indredavik, Bakke et al. 1999). Characteristic ASU features included a standardized acute medical treatment program (leading to increased use of oxygen, heparin, intravenous saline solutions, and antipyretics, and shorter time to stabilization of diastolic blood pressure compared to the GW), early and intensive mobilisation/rehabilitation (leading to shorter time to start of the systematic mobilization/training), an organised team approach that emphasized functional training with both patient and family involvement, and the education of a multidisciplinary team that included integrated physiotherapy and nursing. In contrast, the GW treatment program was characterized by a non-standardized and non-systematic approach, and physiotherapy and occupational therapy were only provided when the ward physician specifically prescribed them. No close co-operation between the physiotherapist and the other staff existed in the GW, where staff were trained to give a generally good quality of care, non-specific to stroke. The shorter time to start of mobilization/training in the ASU was the most important factor associated with discharge to home.

In addition, treatment in combined acute and rehabilitation SU seems to have important long-term effects on outcome for stroke patients. Stroke unit care has been shown to improve survival and functional state and increases the proportion of patients able to live at home at both five (Indredavik, Slørdahl et al. 1997) and 10 years (Indredavik, Bakke et al. 1999) post stroke.

## 2.4 Rehabilitation

### 2.4.1 Overview

Whether in an ASU or a GW, most patients with stroke do not fully recover during acute rehabilitation and there may be diversity in recovery of people with seemingly similar conditions. In addition, while the stroke itself may impose limitations, other factors including medical therapies and the patient's environment may be influential. Once a patient is deemed medically stable, other health professionals become involved in patient management as, because there is no cure, rehabilitation is the most frequent approach to treatment after stroke (Kwakkel, Wagenaar et al. 1999). Rehabilitation is a proactive, person-centred and goal-oriented process that should begin the first day after stroke (Australian National Stroke Foundation 2007) as studies have demonstrated better functional outcome when it is initiated very early (Aborderin 1996). In support of this, a large Canadian retrospective review of 553 stroke patient charts found that patients admitted to stroke rehabilitation within 30 days of first-ever, unilateral stroke experienced greater functional gains (as measured by the Functional Independence Measure) and shorter lengths of stay than those whose admission to rehabilitation was delayed beyond 30 days (Salter, Jutai et al. 2006), with both groups similar in terms of age, gender, side of lesion and the presence of risk factors for stroke. Differences in gender distribution may be important as women have demonstrated poorer outcomes both in terms of disability and rate of institutionalization compared to men (Petrea, Beiser et al. 2009). Long term rehabilitation, taking place in outpatient clinics and in the home occurs later, and has been studied in less detail. The outcomes and cost-effectiveness of treatments are inconclusive (Aziz NA, Leonardi-Bee J et al. 2008).

Rehabilitation aims to improve function and/or prevent deterioration of function, and to bring about the highest possible level of independence – physically, psychologically, socially and financially (Australian National Stroke Foundation 2007). Although a number of organised care models exist (Kalra, Evans et al. 2000),

the central aspect of best-practice rehabilitation is the provision of a coordinated program by specialized, interdisciplinary team of health professionals within a SU (Stroke Unit Trialists' Collaboration 1997; Stroke Unit Trialists' Collaboration 2007). This rehabilitation team involves combined and coordinated use of medical, nursing and allied health skills, along with social, educational and vocational services, to provide individual assessment, treatment, regular review, discharge planning and follow-up (Australian National Stroke Foundation 2007). The objective is to ensure that patients are provided with every opportunity to achieve their maximal potential in terms of physical, cognitive and emotional domains.

#### 2.4.2 Rehabilitation models

Although there is little doubt that an organised multidisciplinary, goal-directed, rehabilitation program is associated with reduced dependency and mortality after stroke (Australian National Stroke Foundation 2007), there is limited evidence about which components of rehabilitation are effective or how intensive and early the intervention should be. Ongoing sub-acute rehabilitation can be provided in a variety of institutional and community based settings. As with acute stroke, rehabilitation outcomes have also been shown to be superior when undertaken in dedicated SUs by trained teams of professionals who use systematic care plans (Aborderin 1996). Stroke units have also been found to be more effective than a specialist stroke team (who consult throughout the hospital facility when bed restraints preclude the patients admission to the specialist SU) or specialist domiciliary care in reducing mortality, institutionalization, and dependence after stroke (Kalra, Evans et al. 2000).

As discussed in Chapter 1 retrospective analysis of components of care in effective stroke rehabilitation units identified at least two different types of SUs (Langhorne and Pollock 2002), dedicated neurological SUs and more generic SUs existing within geriatric rehabilitation units (GRUs). Both are associated with better outcomes for patients with stroke than care in a GW (Foley, Teasell et al. 2003).



#### 2.4.3 Components and intensity of therapy

Rehabilitation is a generic term and specific components including ‘therapy’ have not been well defined (Wade 1999). Physiotherapists are amongst those who make substantial contributions to rehabilitation, specifically in the re-education of all motor functions. These include transfers, walking and the strength and mobility of the trunk and all limbs. Occupational therapists are also involved in the assessment and treatment of motor dysfunction, particularly in relation to its impact on activities of daily living (ADL). They also assess and manage perceptual and cognitive impairment. Speech pathologists assess and treat orofacial dysfunction in relation to the functions of speech and swallowing.

Programs vary greatly from one facility to another as a result of the variable resources available and the individual preference to different treatment concepts and philosophies. Irrespective of the therapeutic approach applied, it is generally accepted that intensive therapy is most beneficial (Kwakkel, Wagenaar et al. 1997) and therapy is more effective if it is task specific (Wagenaar and Meijer 1991).

#### 2.4.4 Age-specific admission criteria

Although data on the influence of age on outcome are inconclusive and there may be no justification to deny patients access to rehabilitation solely because of advanced age (Bagg, Pombo et al. 2002; Black-Schaffer, Winston et al. 2004; Calmels, Defay et al. 2005), some neurological SU facilities have an age-specific ceiling as part of their admission criteria. Justification for this is often the potential incapacity of an elderly cohort to engage in the intensive therapy required for beneficial outcome (Kwakkel, Wagenaar et al. 1997). Geriatric rehabilitation units, by their very nature, tend to undertake the rehabilitation of an older cohort. Age on admission data were collected in the present study in order to correct for differences between the groups at baseline.

There are relatively few studies concerned with the economic implications of stroke care and even fewer for socioeconomic implications (Australian National Stroke Foundation 2007). The comparative cost and effect of two alternative treatments is an important consideration in health care decision-making. The economic burden of stroke is substantial and relates more to the resulting physical disability that dictates length of stay in hospital than the need for prolonged investigation or medical treatment (Wade and Langton 1987). In the longer term, it is the costs related to ongoing care of disabled survivors that dominate including domiciliary support (Bergman, van der Meulen et al. 1995), and this is likely to increase with the increasing number of elderly individuals in the population. It follows that quality outcomes that result in lower readmission and reduce follow-up care required are likely to curtail discounted lifetime costs. For these reasons, it is important that therapy both optimises rehabilitation potential, and does so in the most cost efficient way.

It may be that neurological SUs may pursue higher functional recovery levels (for example, independent ambulation, without walking aid) compared with the GRUs in view of their comparatively younger cohort, who may be expected to live relatively longer, and potentially require return to employment. In order to achieve this, patients may remain inpatients for longer periods of time, and may undertake more extensive therapy sessions (both in terms of frequency and duration of services). Conversely, it may be advantageous for an older person to return home to their familiar environment as soon as possible, and the addition of a walking aid may be an effective way of achieving an early discharge. To date, there have been no studies comparing the rehabilitation outcomes or the direct hospital costs in each of the two settings discussed.

Indicators of cost recorded in the present study were length of stay in the rehabilitation unit and the length of treatment time provided by allied health staff. Although these measures provide only a gross indication of cost difference, this may

be important if there are no significant differences in functional outcome between groups.

#### 2.4.6 Social support

High levels of social support have been associated with faster and more extensive recovery of functional status after stroke and socially isolated patients may be at particular risk of poor outcome (Glass, Matchar et al. 1993). This was relevant to the present study as the SPC SU in Perth is in a central location that may have been further away from the individual patient's home, friends and family. In contrast there are more GRUs – some in outer urban areas - and patients were more likely to be transferred to a unit closer to their home address. It follows that patients transferred to GRUs may be more likely to have more social contact with their friends and family during their rehabilitation stay.

### 2.5 Context of current research

Stroke is a significant cardiovascular event requiring sub-acute rehabilitation, best provided in a SU. Patient factors such as age and social network may influence the choice of facility best suited for an individual to undergo rehabilitation. This study takes its cohort from that group of RPH-WSC patients with stroke in whom the decision as to the type of rehabilitation SU facility preferred was arbitrary, and has provided a direct comparison between the two rehabilitation models for this group of stroke survivors. It has evaluated the differences in the intensity of rehabilitation at each type of facility and the respective benefits in terms of physical and emotional outcomes of patients at 6 and 12 months post-stroke.



## CHAPTER 3

### PILOT STUDIES

#### 3.1 Introduction

##### 3.1.1 Facilities

The majority of metropolitan adult patients with stroke in Perth, Western Australia are admitted and treated in one of three tertiary teaching hospitals. These are the Royal Perth Hospital – Wellington St Campus (RPH-WSC), Sir Charles Gairdner Hospital (SCGH) and Fremantle Hospital (FH). In addition, there are emergency departments at 5 other hospitals (Armada-Kelmscot, Joondalup, Bentley, Murdoch and Swan) responsible for the acute management of some stroke patients.

This study involves those patients with acute stroke admitted and treated at the RPH-WSC. Within this hospital, there are a number of medical specialties able to manage this group. Management is triaged in the emergency department, based on the age of the patient, the number of co-morbidities, the degree of impairment, and the prognosis for recovery. The majority of patients with stroke are managed in the acute stroke unit (ASU), the neurology and neurosurgery wards, the general medical wards, or the geriatric wards where medical and nursing staff are responsible for the initial stability of the patient.

##### 3.1.2 Number of Stroke Patients

Between July 1999 and June 2000, 531 patients with stroke presented to RPH-WSC. The medical specialties undertaking case management are summarized in Figure 3.1.2a. Almost half these patients (n=221) were assessed and treated in the ASU. Discharge destination of the whole cohort is summarized in Figure 3.1.2b, with 204 patients requiring transfer to other facilities for ongoing rehabilitation. For the 221 inpatients managed by the ASU, discharge destination varied (Figure 3.1.2c) with 95

patients discharged to another hospital or institution for rehabilitation. Of these, 64 were aged  $\geq 60$  years. Forty-eight were transferred to SPC stroke unit (SU), with 24, aged  $\geq 60$  years. Another 40 patients were transferred to geriatric rehabilitation units (GRUs) (Bentley, n=18; Mercy, n=16 and Swan, n=6), all aged  $\geq 60$  years.

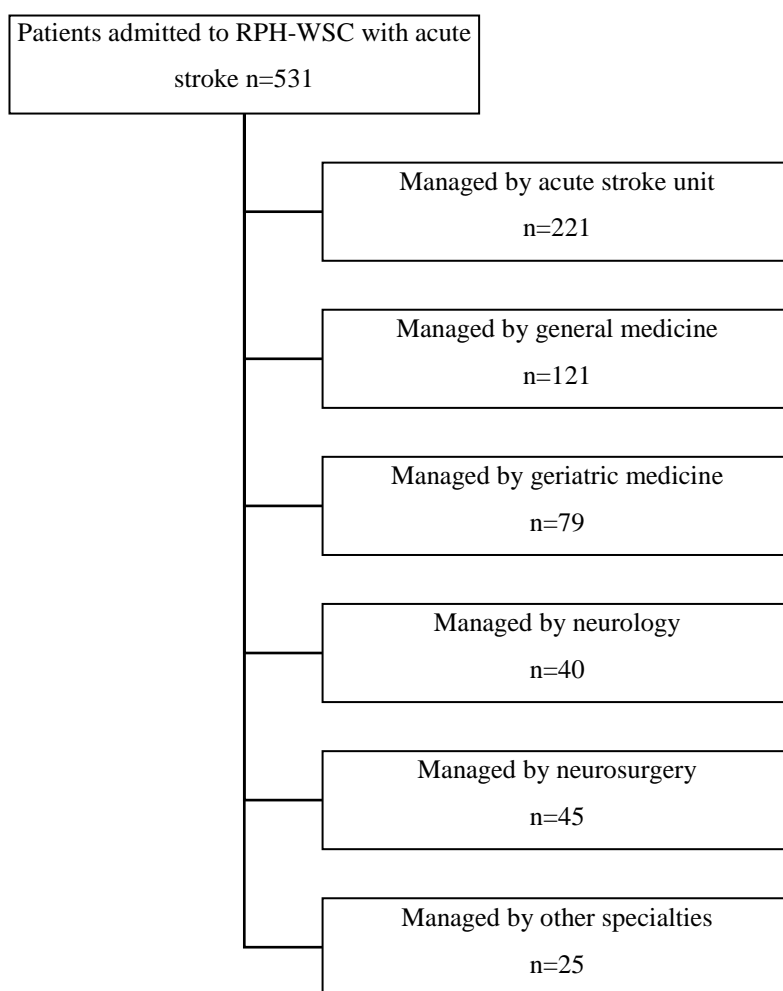


Figure 3.1.2a: Inpatient destination of patients with Stroke following admission to RPH-WSC between July 1999 and June 2000

**RPH-WSC= Royal Perth Hospital-Wellington Street Campus**

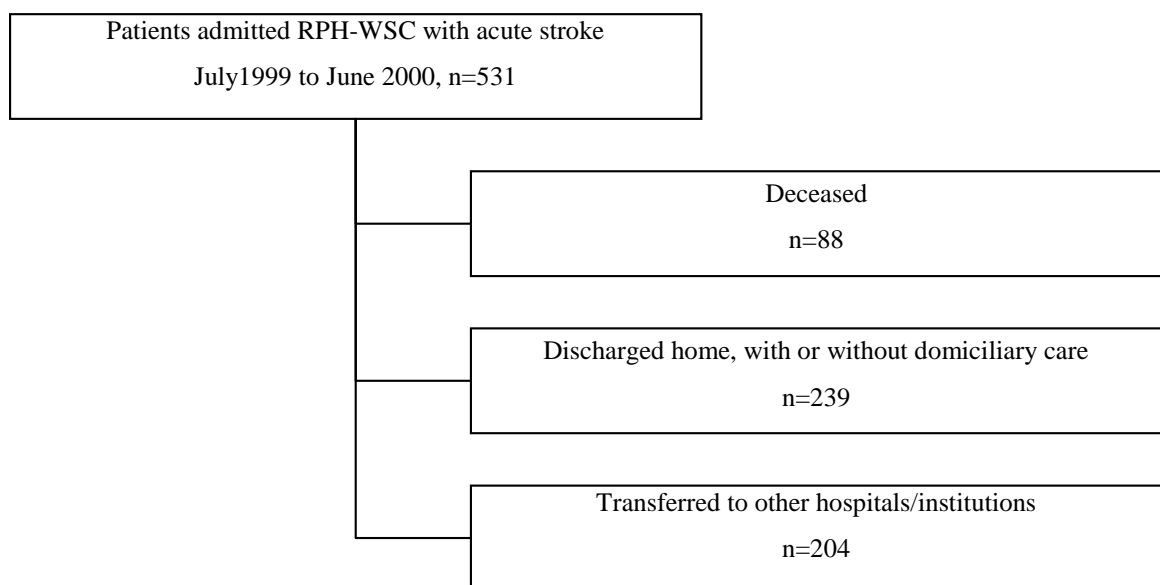


Figure 3.1.2b: Discharge destination of patients with Stroke following admission to RPH-WSC between July 1999 and June 2000

**RPH-WSC= Royal Perth Hospital-Wellington Street Campus**



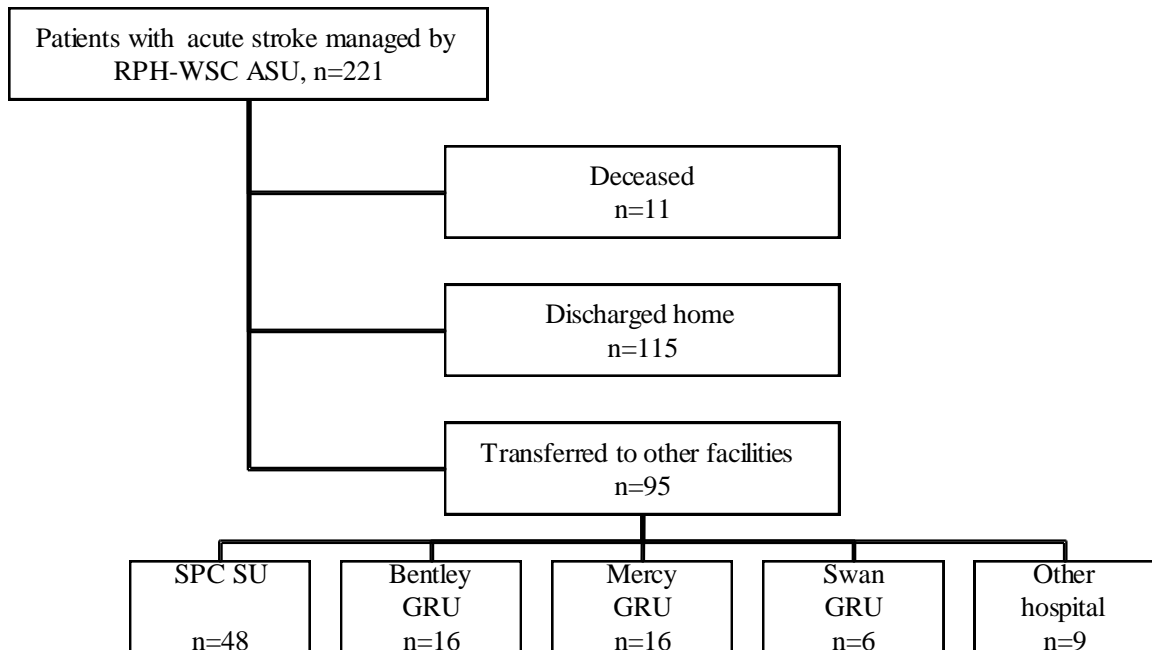


Figure 3.1.2c: Discharge destination of patients with Stroke cared for by the RPH-WSC ASU following admission between July 1999 and June 2000

**RPH-WSC= Royal Perth Hospital –Wellington Street Campus; ASU=Acute Stroke Unit; SPC= Royal Perth Hospital – Shenton Park Campus; GRU=Geriatric rehabilitation unit**

### 3.1.3 Rehabilitation

As discussed in Chapter 2, the rehabilitation of stroke is complex (Pomeroy and Tallis 2000) and different types of facilities provide different emphasis and care (Langhorne and Pollock 2002). Anecdotally in our city, more young patients with fewer co-morbidities are managed by neurologists at the SPC SU, and undergo high intensity rehabilitation. Older patients who have more co-morbidities and are less capacity to cope with an intensive rehabilitation program are rehabilitated under the care of geriatricians on GRUs. These units include ward 4 at Bentley health service (Bentley), and the restorative units at Mercy hospital (Mercy) and Swan health service (Swan).

The allocation to one type of facility over the other based solely on age may be quite clearly defined, but there remains a group of mid-aged stroke patients with both the potential to return to some form of independent living as well as the ability to cope with intensive rehabilitation where the age factor may be less definitive. For example, an older individual with few co-morbidities and small stroke, or a younger individual with significant co-morbidities and large stroke could justifiably be sent to either type of facility. As a consequence, in this group, allocation to one type of rehabilitative facility over another may be more random, with no objective evidence to suggest advantages of stroke rehabilitation under one model or other. This uncertainty may also be influenced by a perception that the organisation and delivery of rehabilitation services is fundamentally different between these facilities. These patients in the “grey” area are the ones of particular interest in this study.

Progressive pilot studies were undertaken between 2001 and 2004 in order to explore whether this perception of difference between facility type was true, and to identify trends in a pilot sample that could be tested in a larger population of patients with stroke. Pilot studies were also used in order to develop tools to measure potential differences in the organisation and delivery of rehabilitation services between the two different types of facility.

Although the hypothesis was that there would be no significant differences between facilities, the sample size of the pilot data was too small to generate meaningful results. These studies were also not designed in order to gather data to power the final study (which was to be powered using other previously validated robust rehabilitation outcome measures).

#### 3.1.4 Tools

Allied health professional (AHP) questionnaires (3.2.1) were developed to establish whether or not the perceptions held by incumbent AHPs at the different facilities demonstrated differences in terms of the environment and approach to treatment that

rehabilitation offered at their facility. The questionnaires were pilot tested at the facilities receiving RPH-WSC stroke patients (seen in Figure 3.1.2c). Differences in frequency and intensity of treatment highlighted here led to the development and trial of patient diaries (3.2.2) to record the frequency and duration of patients' daily rehabilitation, including details of which professionals provided the interventions. To further capture differences in the quantity of rehabilitation and the environment in which it was undertaken, behaviour mapping (of both individual stroke patients, and the ward as a whole) was then developed and trialed (3.2.3) as a tool for implementation during the period of the Stroke Rehabilitation Outcome (SRO) Trial.

## 3.2 Pilot Studies Undertaken

### 3.2.1 Allied Health Professional (AHP) Questionnaire

#### 3.2.1.1 Introduction

During 2001, an AHP questionnaire was developed in order to determine the experience, education and training, treatment philosophy and workload of AHP staff at four facilities involved in the rehabilitation of RPH-WSC acute stroke patients. The questionnaire also examined the individual's perception of the care provided by both them and their facility, and the amount of influence they felt they had on patient length of stay. The hypothesis was that there would be significant differences in these factors between facilities.

#### 3.2.1.2 Development of tool

##### Method

The 18-question survey (Appendix 1) developed comprised 4 tick-box questions, 8 close-ended questions and 3 open-ended questions. There were also 3 100millimetre visual analogue scales (VAS) where AHPs indicated their philosophy of therapy, in terms of it being compensatory (0) or facilitatory (100), and the level of care they provided as individual health professionals and their facility as a whole to patients with stroke, where 100 was optimal.

## Trial

The questionnaire was trialed by AHPs employed at SCGH. Questionnaires were distributed to 8 AHPs at this facility, at various levels of appointment, all working in neurology (3 physiotherapists, 3 occupational therapists, and 2 speech pathologists). Questionnaires were returned by mail to the investigator. Responses were validated by individual telephone interviews with the respondents on receipt of their completed questionnaires.

## Results

All questionnaires were returned, and all respondents completed the questionnaire in less than 10 minutes. None found any questions ambiguous, and discussion with respondents suggested that their interpretation was consistent with the intention of the questions. Although respondents understood the visual analogue scale question regarding philosophy of treatment, they suggested that an additional question regarding the breakdown of treatment philosophy might be useful. It became evident that there was no question that quantified whether or not workload reflected employment status (full or part time), and no question regarding involvement in research.

## Discussion

The revised questionnaire used for pilot testing included an additional 3 questions (Appendix 2). These ascertained employment full time equivalency (FTE), research experience, and a percentage breakdown of treatment philosophy according to well established neurological rehabilitation approaches (in addition to the VAS question). In addition to the VAS, room was provided for comments regarding the perception of care.

### 3.2.1.3 Implementation of the tool

Questionnaires were distributed to all incumbent AHPs on the rehabilitation wards at each of the 4 facilities involved with the SRO Trial. Participants were told about the study by telephone, and return of the completed questionnaire inferred consent.

### 3.2.1.4 Results of the pilot study

Questionnaires were completed by 29 out of 30 AHPs across the four facilities surveyed. The cohort included physiotherapists, occupational therapists and speech pathologists. In view of the small sample size, only descriptive statistics have been used to summarize the data.

#### AHP Experience, Education and Research

Responses that characterize the AHPs are summarized in Table 3.2.1.4a. The majority worked fulltime (69%) on inpatient rehabilitation wards (72%). Staff at SPC SU attended ongoing education of any kind more frequently (at least weekly) than any other facility. Across all sites, only 9 AHPs had enrolled in some form of postgraduate study with only 4 completing a postgraduate qualification. Only SPC SU AHPs had been involved in research.

At least one AHP at every facility had more than 20 years post-graduate general experience, with Mercy staff having the highest median experience of 18 years (range 10-25) (Figure 3.2.1.4a). The experience of staff in the specific treatment of stroke patients varied considerably between facilities (Figure 3.2.1.4b), with Mercy again having the highest median experience of 156 months (range 36 – 204). SPC SU had the lowest median (24 months; range 1-324).

Table 3.2.1.4a: Characteristics of Allied Health Professional (AHP) respondents, n (%).

|                          | SPC<br>SU<br>n=9 | Bentley<br>hospital<br>GRU<br>n=11 | Mercy<br>hospital<br>GRU<br>n=3 | Swan<br>hospital<br>GRU<br>n=6 | Total<br>n=29 |
|--------------------------|------------------|------------------------------------|---------------------------------|--------------------------------|---------------|
| Allied Health Profession |                  |                                    |                                 |                                |               |
| Physiotherapist          | 5 (56)           | 6 (55)                             | 1 (33)                          | 2 (33)                         | 14 (48)       |
| Occupational Therapist   | 4 (44)           | 2 (18)                             | 1 (33)                          | 3 (50)                         | 10 (34)       |
| Speech Pathologist       | 0                | 3 (27)                             | 1 (33)                          | 1 (17)                         | 5 (18)        |
| Location                 |                  |                                    |                                 |                                |               |
| Rehabilitation ward      | 8 (89)           | 4 (36)                             | 3 (100)                         | 6 (100)                        | 21 (72)       |
| Day Hospital             | 1 (11)           | 5 (46)                             | 0                               | 0                              | 6 (21)        |
| Both                     | 0                | 2 (18)                             | 0                               | 0                              | 2 (7)         |
| Fulltime equivalency     |                  |                                    |                                 |                                |               |
| Fulltime                 | 7 (78)           | 10 (91)                            | 1 (33)                          | 2 (33)                         | 20 (69)       |
| Part time                | 2 (22)           | 1 (9)                              | 2 (67)                          | 4 (67)                         | 9 (31)        |
| Continuing Education     |                  |                                    |                                 |                                |               |
| Twice weekly             | 3 (33)           | 0                                  | 0                               | 0                              | 3 (10)        |
| Weekly                   | 6 (67)           | 0                                  | 1 (33)                          | 0                              | 7 (24)        |
| Fortnightly              | 0                | 0                                  | 0                               | 2 (33)                         | 2 (7)         |
| Monthly                  | 0                | 2 (18)                             | 0                               | 1 (17)                         | 3 (10)        |
| Six monthly              | 0                | 7 (64)                             | 2 (67)                          | 2 (33)                         | 11 (39)       |
| Annually                 | 0                | 2 (18)                             | 0                               | 1 (17)                         | 3 (10)        |
| Postgraduate study       | 2 (22)           | 3 (27)                             | 1 (33)                          | 3 (50)                         | 9 (31)        |
| Research Involvement     | 4 (44)           | 0                                  | 0                               | 0                              | 4 (14)        |

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit**

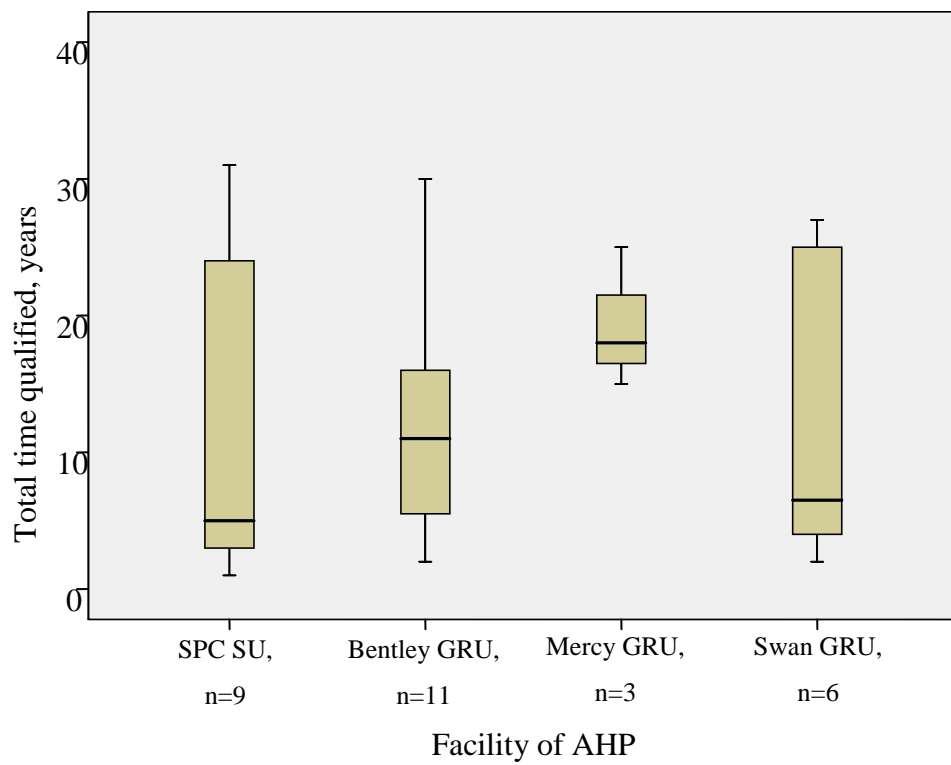


Figure 3.2.1.4a: Years since qualification for staff at each facility

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

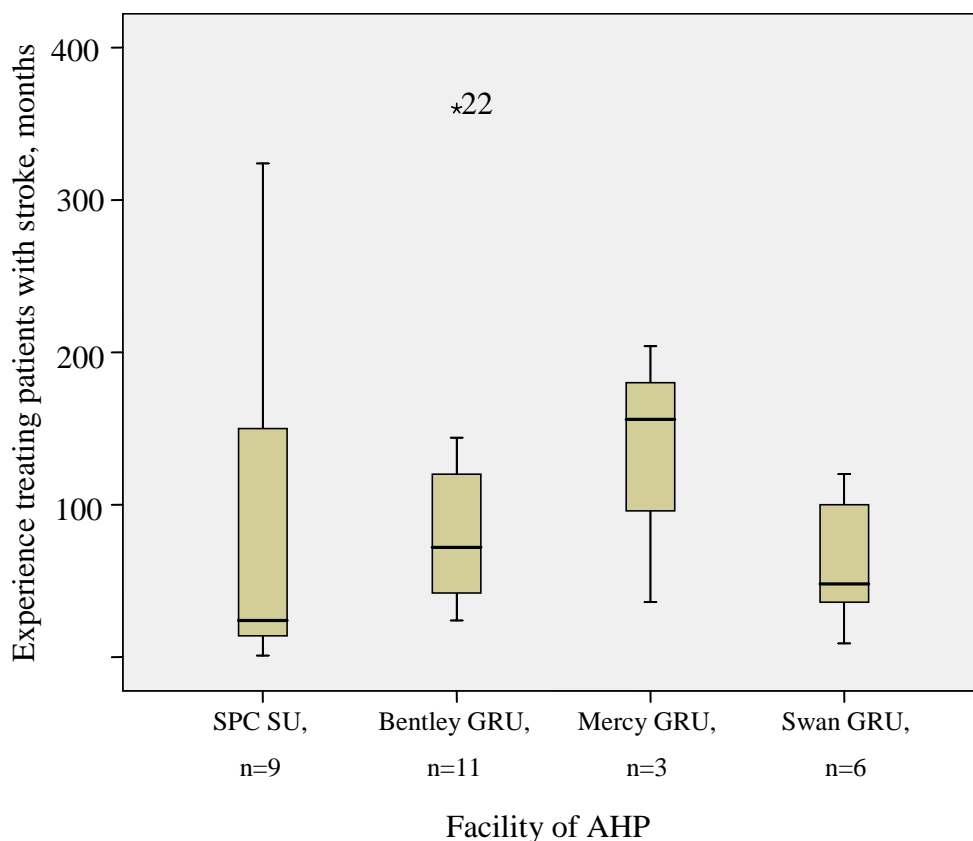


Figure 3.2.1.4b: Individual AHP's experience treating patients with stroke, months

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

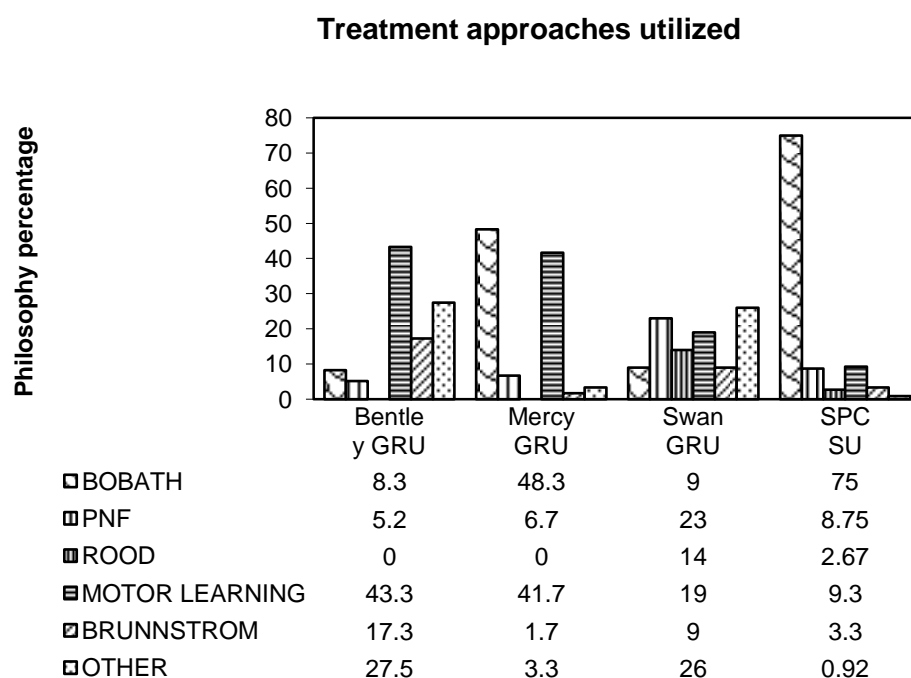
In summary, whilst all facilities had some longstanding senior staff, SPC SU, Bentley and Swan also had a number of rotating junior staff. The number of junior staff was reflected in the median amount of specific stroke rehabilitation experience across facilities, with SPC SU recording the lowest level of experience. They also had the highest rate of continuing education and research involvement compared with all of the other facilities. Post-graduate enrolments were equally spread over facilities.



### AHP Treatment Philosophies

Shenton Park Campus SU staff perceived that they were more facilitatory in their treatment approach (mean 80.65 on 100millimetre VAS) than staff at the other facilities (mean 50.44 at Bentley, mean 59.98 at Swan, data not provided by Mercy). In terms of the philosophy of treatment approaches, the Bobath Concept was more widely embraced (75% of overall approach) at SPC SU than at the other facilities (range 8.3 - 48.3%). At other facilities, there was more emphasis on combined approaches for the management of comparable patient groups (Table 3.2.1.4b).

Table 3.2.1.4b: Proportions of different treatment philosophies utilised at each facility



**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit**

#### Workload and casemix

AHPs at Swan reported a consistently higher (median 12 IQR 4) number of treatments per day than AHPs at SPC SU, Bentley and Mercy who treated a similar number of patients each day (median (IQR) 8 (5), 9(10) and 8 (10.5) respectively) (Figure 3.2.1.4c). AHPs at SPC SU treated more patients with stroke per day (median 6, IQR 2.5) (Figure 3.2.1.4d) and therefore also spent the most time treating patients with stroke each day (median 360 minutes, IQR 180) (Figure 3.2.1.4e). The duration of a treatment session for stroke patients however was similar across facilities (median 60 minutes) (Figure 3.2.1.4f).

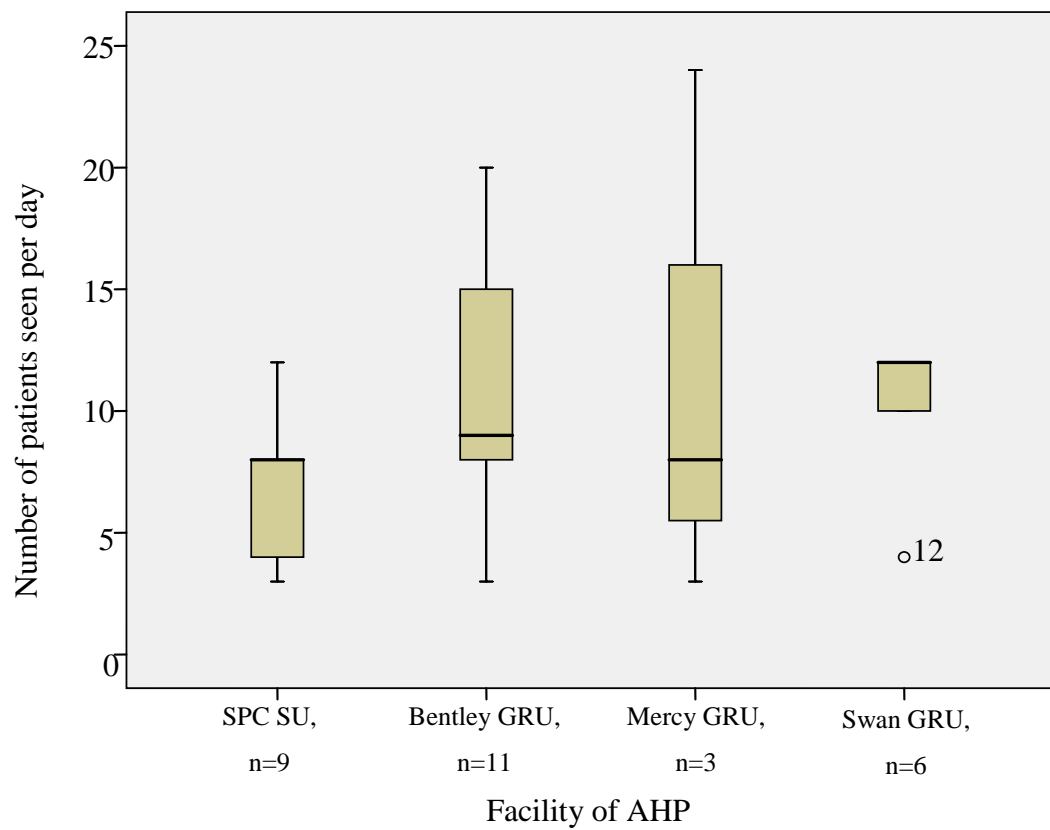


Figure 3.2.1.4c: Number patients seen per day at each facility

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

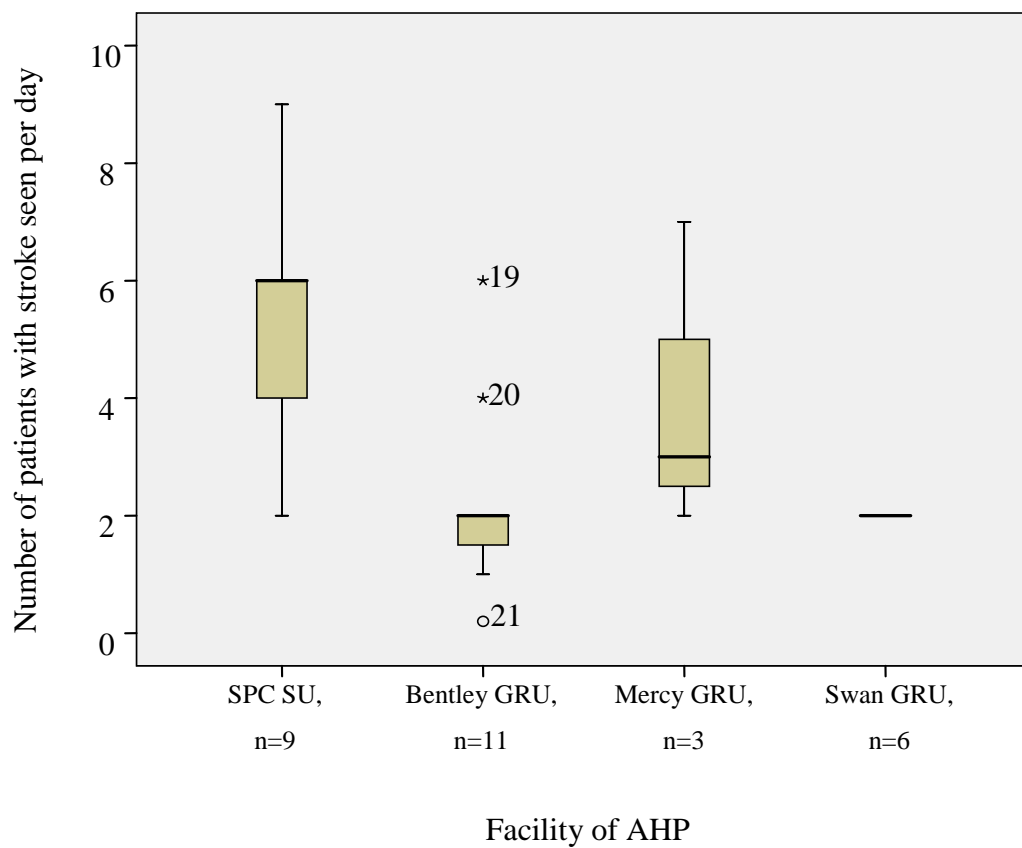


Figure 3.2.1.4d: Number of stroke patients seen per day at each facility

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

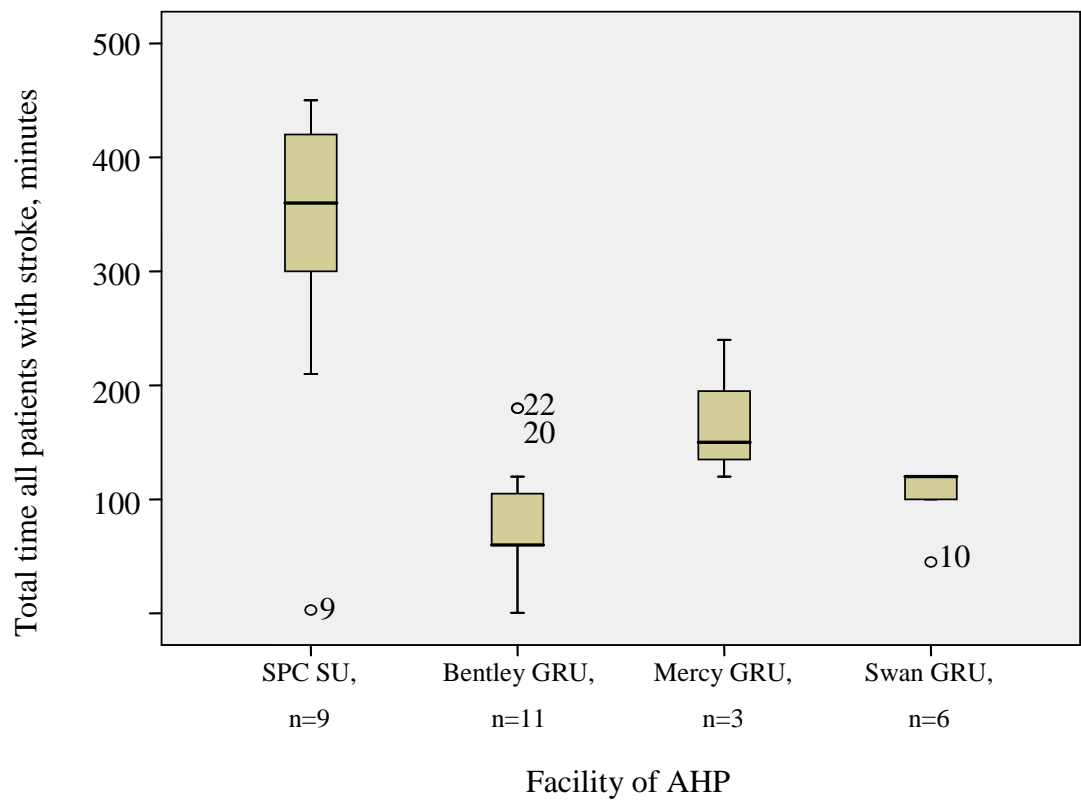


Figure 3.2.1.4e: Time AHP treats all patients with stroke per day, minutes

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

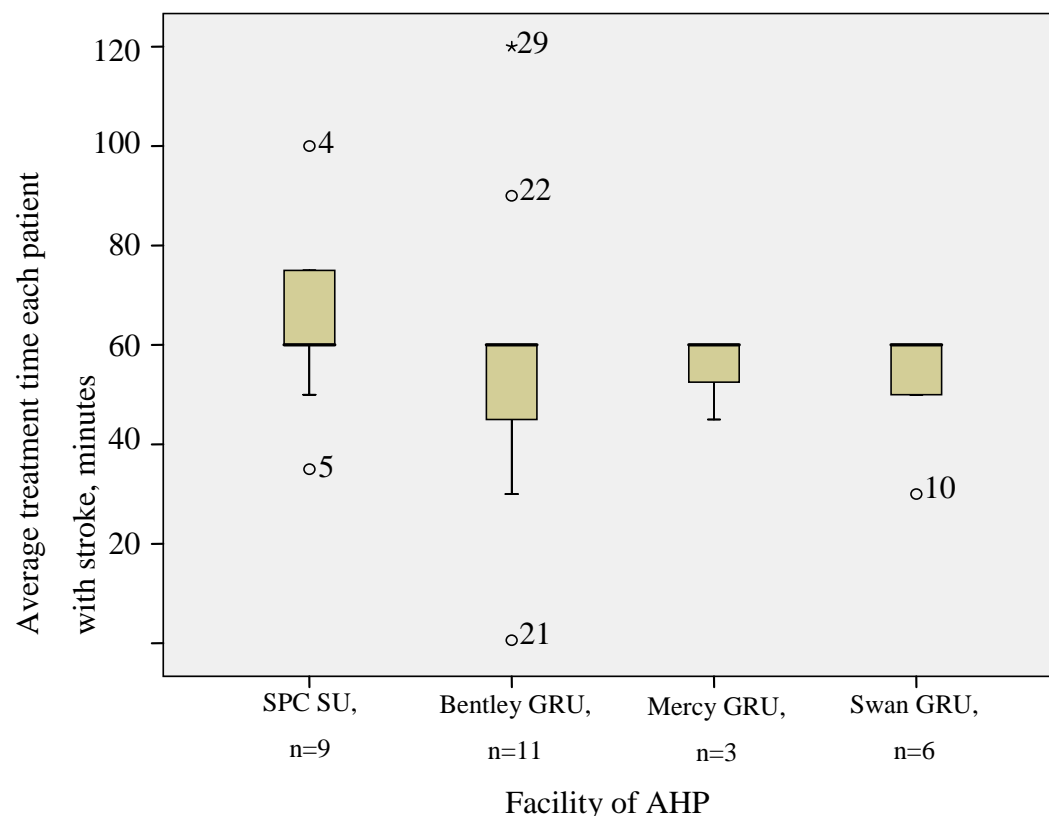


Figure 3.2.1.4f: Average treatment time per patient with stroke, minutes

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

#### Care Provided

At SPC SU, Bentley and Swan respondents perceived the level of care provided by AHPs was higher (median rated 81, 76 and 80 respectively on 100millimetre VAS) compared with Mercy (median rated 64) and the reasons provided for “less than optimal care” included lack of resources, lack of experience, and workload and time restraints. Respondents from Mercy did not specify any factors impinging on the level of care provided (Figure 3.2.1.4g). SPC SU and Swan perceived a higher level of overall care by their facility (median rated 86 by both on 100millimetre VAS) compared with Bentley and Mercy (median rated 75 and 74 respectively) (Figure 3.2.1.4h).

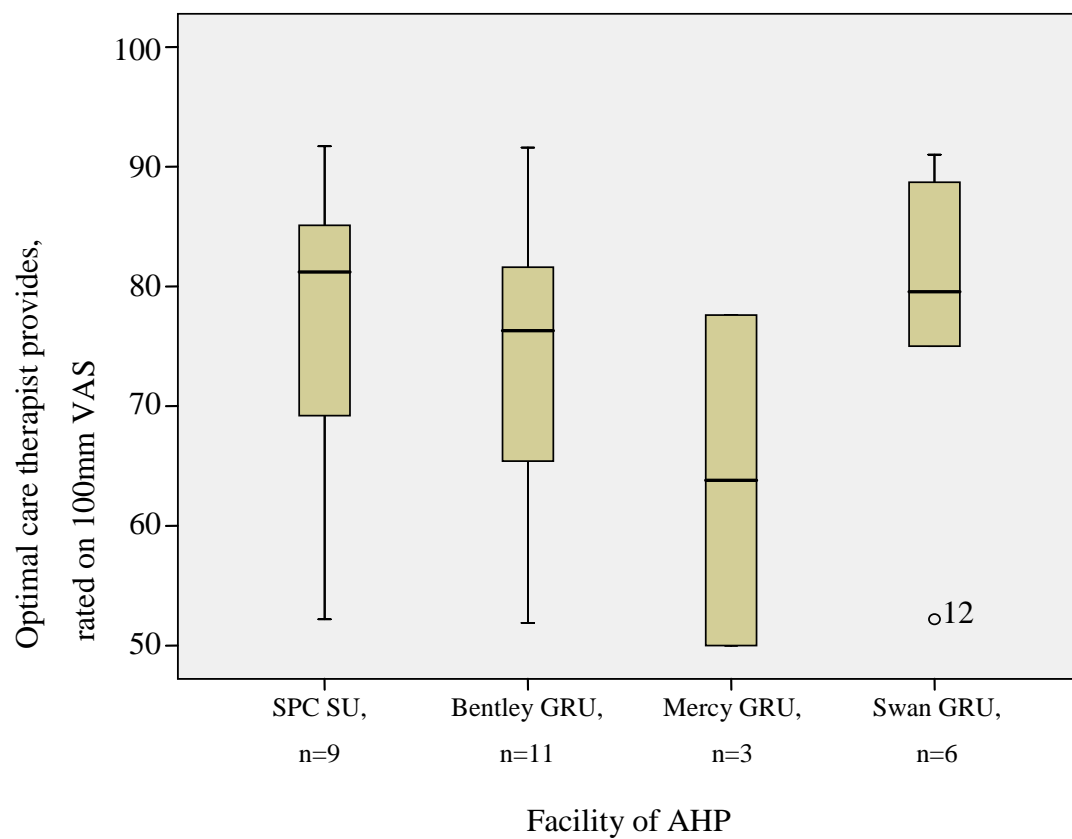


Figure 3.2.1.4g: Perceived rating of AHPs optimal care, rated on 100mm VAS

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

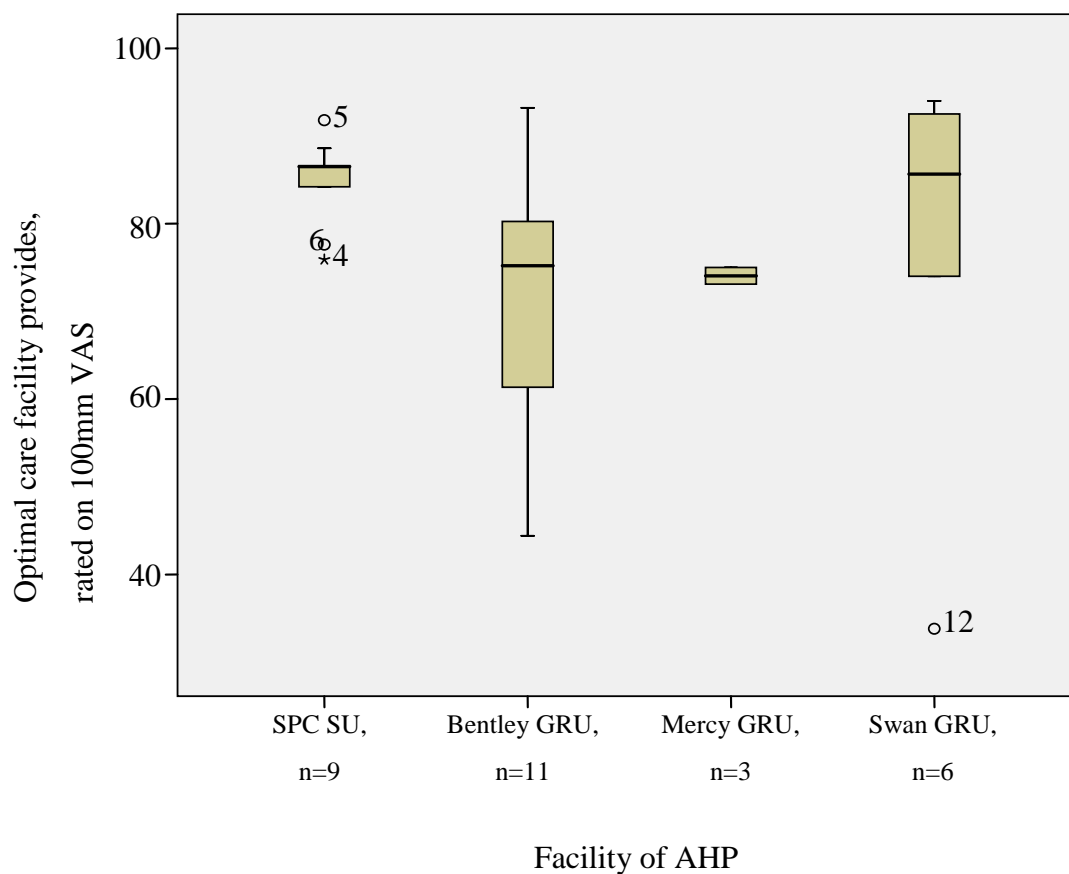


Figure 3.2.1.4h: AHP's perception of facility's optimal care, rated on 100mm VAS

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional; VAS=visual analogue scale**



### Length of Stay (LOS)

AHPs reported that LOS in days (mean, range) for patients with stroke were similar at SPC SU (75, 60-90) and Bentley (70, 52-100), while LOS at Mercy (41, 40-84) and Swan (50, 21-90) were somewhat shorter. AHPs at all facilities had comparable influence over stroke patient LOS at their facility, with 78% of all respondents having more than moderate or maximal input (Table 3.2.1.4c).

Table 3.2.1.4c: AHP level of influence on patient LOS, n (%)

|                    | RPH-SPC | Bentley | Mercy  | Swan    | Total   |
|--------------------|---------|---------|--------|---------|---------|
|                    | n=8     | n=6     | n=3    | n=6     | n=23    |
| Level of input     |         |         |        |         |         |
| Minimal            | 1 (12)  | 1 (17)  | 0      | 0       | 2 (9)   |
| Moderate           | 2 (25)  | 1 (17)  | 0      | 0       | 3 (13)  |
| More than moderate | 5 (63)  | 2 (33)  | 2 (67) | 6 (100) | 15 (65) |
| Maximal            | 0       | 2 (33)  | 1 (33) | 0       | 3 (13)  |

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional; LOS=length of stay**

### 3.2.1.5 Discussion and Summary

Using this self-reporting approach, there were clear differences in the 4 rehabilitation wards themselves and the AHPs who staff them. One of the major areas of difference between facilities appeared to be the treatment philosophy, however it became obvious from the responses that every AHP's interpretation of what was "facilitatory" and what was "compensatory" was not always the same. One respondent indicated, for example, that they were very facilitatory in their philosophy, utilizing a high level of Brunstrom and Motor Learning in their approach. Another respondent said that they were also largely facilitatory, utilizing the Bobath approach almost always. It is clear to most AHPs that these approaches are somewhat polarized on the facilitatory continuum, there remains debate as to which of the two treatment philosophies is facilitatory.

More than 60% of AHPs from all facilities felt that they had more than moderate influence over stroke patient length of stay at their facility. This may reflect the general high regard in which they are held for their role in the rehabilitation of patients with stroke. Moreover, they felt that within some constraints (including lack of resources, lack of experience, and workload and time limits), as individuals and as a facility they provided better than average care for the rehabilitation of patients with stroke.

#### 3.2.1.6 Implications for SRO study

These preliminary findings suggested that there were differences in the self report of experience, training, treatment philosophy and workload of AHP staff at four facilities involved in the rehabilitation of stroke patients referred from RPH-WSC. Whilst a self-reported questionnaire was adequate to validate the Investigator's perception, a more objective tool was needed for the final study, and this led to the development and pilot testing of patient diaries.

## 3.2 Pilot Studies Undertaken

### 3.2.2 Patient Diaries

#### 3.2.2.1 Introduction

A patient diary was developed in order to examine variations in rehabilitation practices and to establish if there was a difference in the way stroke patients were managed at four facilities involved in the rehabilitation of RPH-WSC ASU patients. The aim was to measure the frequency and duration of treatment sessions, record the profession and level of appointment of the AHP performing the treatment and differentiate between individual or group sessions. The hypothesis was that there would be significant differences across all of these domains between facilities.

#### 3.2.2.2 Development of tool

##### Diary Design

In consultation with various AHP team members experienced in stroke rehabilitation, items in the diary were determined by the objectives of the pilot study. It was decided that the most practical size and format would be an A5 booklet. The cover was to be a bright colour so that it could not easily be lost on the ward. This booklet would include 4 separate pages for each major AHP group involved in the rehabilitation of stroke patients. These were deemed to be physiotherapists, occupational therapists, speech pathologists, social workers, and “others” (which was to include any other groups such as dieticians and podiatrists). These pages would be colour coded to differentiate between professional groups.

In each of these professional sections, tables were devised so that AHPs could identify themselves (and thereby their level of appointment), the date, the frequency and length of contact with the patient, whether treatment was undertaken in a group or individually, and whether or not the interaction was directly related to treatment or the administrative tasks relevant to patient care. An extract of the diary is shown in Figure 3.2.2.2a.

Figure 3.2.2.2a: Extract from pilot patient diary

| Date     | Initials<br>of<br>therapist | THERAPY Time<br>(minutes)<br>Spent with patient<br>over the number of patients<br>concurrently in therapy area | ADMINISTRATION Time (minutes)<br>Spent away from patient on<br>patient notes, general paper work, or<br>ward rounds |
|----------|-----------------------------|--|---|
| 04/06/04 | DD                          | 45/3<br>(45 minutes spent with this pt<br>whilst 2 others pts in gym)  |   |
| 04/06/04 | DD                          |  | 5   |

#### 3.2.2.3 Implementation of tool

All AHPs treating stroke patients at their facility agreed to participate in the pilot study. They were educated in recording their interventions in the pilot diary at in-service presentations at each facility.

Twelve patients (3 at each facility) volunteered for the pilot study and provided written informed consent (Appendix 3). The only selection criteria were that they were newly diagnosed with stroke, and were receiving some level of input from the AHPs. The patients were provided with a pilot diary that was kept at a location mutually convenient to all incumbent AHPs. This location was individualized for each facility, and decided upon following discussion and trial with the subjects and AHPs concerned.

#### Data collection

Incumbent AHPs recorded data for 5 weekdays. Diaries were then collected for review by the investigator. Informal discussions were then held between the investigator and incumbent AHPs regarding the ease of completion, and usefulness of the information generated.

#### 3.2.2.4 Results of pilot study

During 2004, pilot data were collected from 12 stroke patients, 3 from each of the four facilities receiving RPH-WSC ASU patients, using purpose designed patient diaries.

All diaries were fully completed by the AHP team. None were misplaced or lost on the ward during the trial. The manner in which the diaries were managed on individual wards was individualized for each facility. At SPC SU, it was found most effective if the diary remained attached to the patient's wheelchair, or if no wheelchair, in their bed space. The patient was then responsible for the whereabouts

of the diary. At Bentley and Swan, the diary remained with the patient's observation charts at the bedside. At Mercy, the diary remained with the AHPs.

The diaries were found to be effective in measuring the frequency and duration of treatment and the characteristics of the AHPs attending. These data indicated differences between facilities in terms of individual AHP interventions. Specifically:

Although total administrative times were similar, there were differences in the total time spent with the three patients across facilities, with SPC SU spending considerably more time than the other facilities (total minutes SPC SU=2320) (Figure 3.2.2.4a).

Mercy had a higher total number of occasions of service (74) compared with the other facilities that were similar to each other (Figure 3.2.2.4b). There were variable amounts of interventions of all AHP groups other than physiotherapy at each facility (Figure 3.2.2.4b).

There were clear differences across facilities in terms of the levels of appointment of the AHPs providing the occasions of service (Figure 3.2.2.4c). There was no senior staff at Bentley, no junior staff at Swan and no students at either Mercy or Swan. All facilities utilized therapy aides.

There were also differences between the setting in which contact took place (Figure 3.2.2.4d). The majority of Bentley (95%) and Mercy (81%) occasions of service took place in isolation, with a much smaller proportion occurring in a group setting. SPC SU and Swan had almost equal occasions of service in isolation and in group settings.

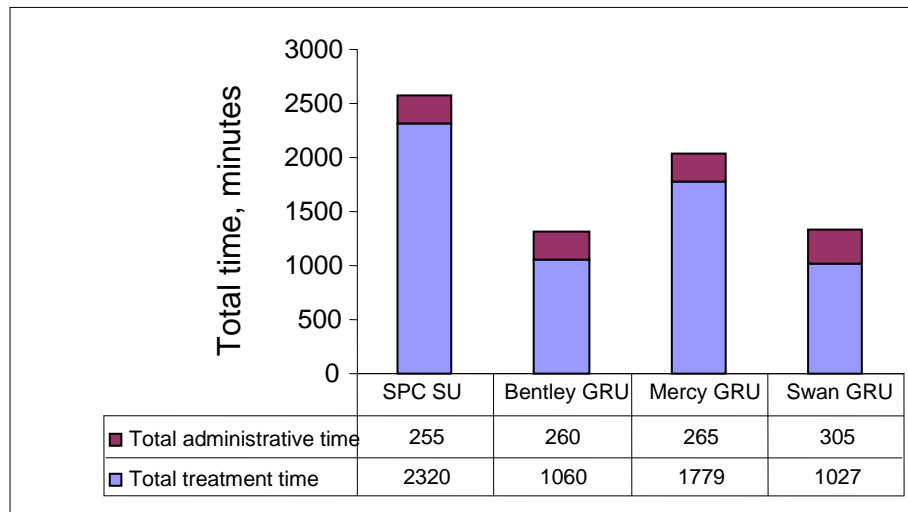


Figure 3.2.2.4a: Breakdown of treatment and administrative time from 12 patient diaries, minutes

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

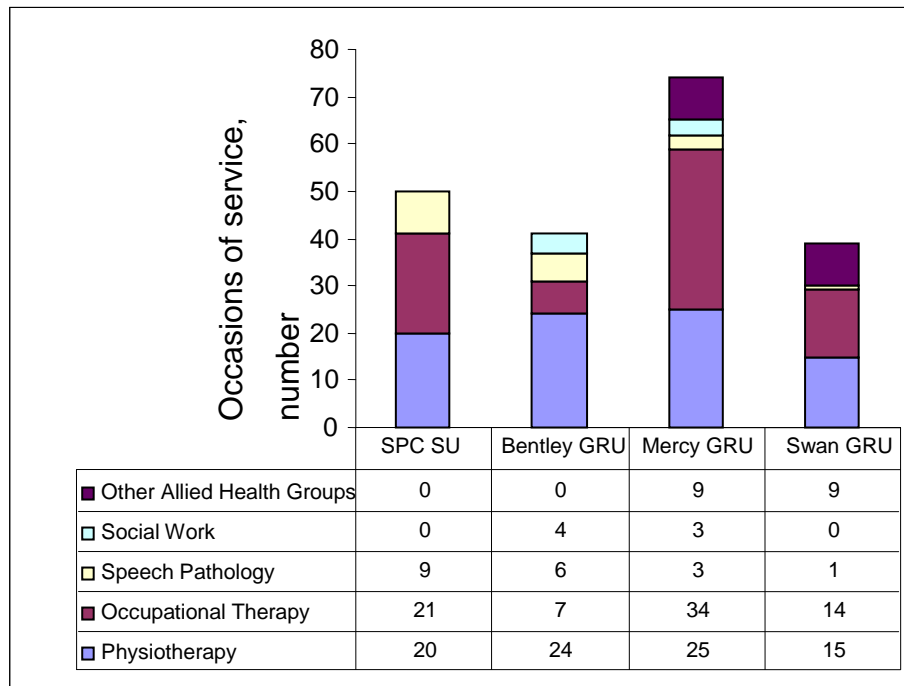


Figure 3.2.2.4b: Total occasions of service from 12 patient diaries by AHP

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**



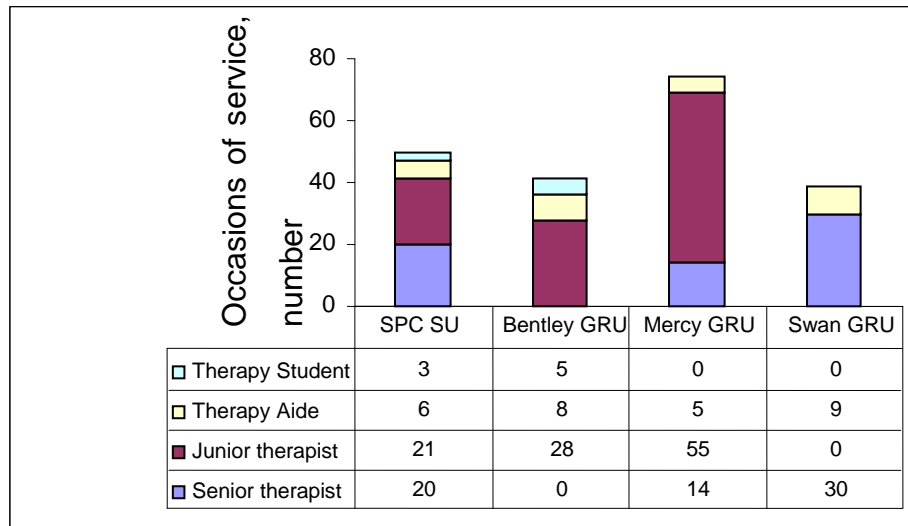


Figure 3.2.2.4c: Total occasions of service from 12 patient diaries by level of AHP appointment

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

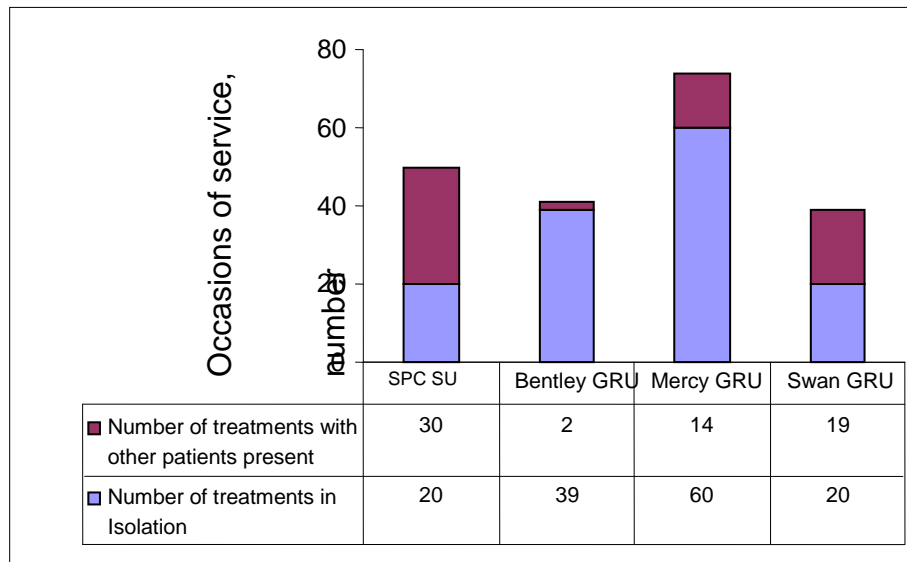


Figure 3.2.2.4d: Breakdown of individual and group treatments from 12 patient diaries

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

### 3.2.2.5 Implications for main study

All AHPs found the diaries straightforward to complete. Following analysis of the data entered by AHPs, and their direct feedback, some changes were made for the final SRO Trial patient diary (Appendix 4). An additional column in the daily treatment area was added where AHPs could indicate the location of the intervention, and space was also provided to differentiate between administration time (involving paperwork and recording of statistics) versus ward rounds and meetings.

Utilization of patient diaries on the rehabilitation wards was feasible, and the data collected was useful and informative. Based on the information already collected from AHP questionnaires, it was not surprising that the diary data suggested differences between the facilities in terms of AHP attendance, and the treatment frequency and duration in stroke rehabilitation. Patient diaries were a valuable tool to measure these differences and were therefore considered to be useful for the main study following the minor changes outlined.

Although the individual patient intervention would now be measured, the environment in which the rehabilitation took place had not been objectively defined. This led to the development of ward behaviour mapping that will be discussed next.

## 3.2 Pilot Studies Undertaken

### 3.2.3 Behaviour Mapping

#### 3.2.3.1 Introduction

Behavioural mapping has been used since the 1970's (Fairbanks, McGuire et al. 1977; Keith 1980; Keith and Cowell 1987) to measure activity patterns, time usage, and thereby the culture and the functional organization of a facility. It involves observational study whereby subjects are monitored for specific time periods during daily activities.

In health, studies of time have historically focused on observation of health care providers, and their efficiency in the delivery of services to patients under their care. The number of health professionals involved in the rehabilitation of patients with stroke may be considerable, and another approach is to observe the patients themselves.

Previous studies in the observation of patients with stroke have focused on the static time patients were seen in solitary behaviour, treatment behaviour or social behaviour (Keith 1980; Lincoln, Gamlen et al. 1989; Tinson 1989), and the specific activities undertaken at the time of observation (Newall, Wood et al. 1997; Ada 1999). Results have shown that formal therapy occupies a small portion of patients' average day and many patients remain solitary and inactive for long periods.

What was needed for this trial was a tool to measure the ward environment in terms of the location, activity and interactions of inpatients at each of the four study facilities.

### 3.2.3.2 Development of tool

#### Behaviour Mapping Design

Four customized topographical ward maps were designed by walking around the ward and treatment areas at each facility. These were drawn freehand, approximately to scale. They included the physical layout of the ward (room positions, the location of toilets, showers, lounge and dining areas, nursing and medical stations), as well as the number of patients normally allocated to each room. Each form also had generic close-ended questions regarding the number of empty beds, the total number of patients, and the total number of stroke patients on that unit, on that day. These maps were to be utilized for “topographical” mapping (Appendices 5 and 6).

In addition, patient-based behaviour maps were designed so that the individual patient’s category of behaviour and, if receiving therapy, the nature of the intervention (including the discipline, the location, the philosophy applied and the presence of others) could be recorded (Appendix 7).

#### Assessment of Daily Routine

A ward familiarisation process involving consultation with incumbent ward AHPs and clerks at each facility provided details of the day to day ward routines including the room allocation system, patient treatment programming, and areas where treatment interventions were actually carried out was undertaken. This enabled the observer to locate all ward patients efficiently on a 15-minute walk-through the ward and rehabilitation areas.

Patient information, consent forms and Therapist information (Appendices 8-10) forms were developed. A generic daily routine template (Appendix 11) was also devised in order to utilize time most efficiently, and provide as many maps as possible between the hours of 0830 and 1630. Five topographical maps and 4 patient-based maps were scheduled over the period. Utilizing this form, the observer

could plan each day and rotate the observation order of the subjects such that they were not observed at exactly the same time each day.

Each topographical map had an additional demographic template in the top left hand corner (Appendix 5). This template enabled details of the number of beds, number of empty beds, number of patients and number of patients with stroke to be recorded at the beginning of each episode of mapping.

The categories of behaviour used in a 1988 study of patients with spinal injury (Kennedy, Fisher et al. 1988) (Table 3.2.3.2a) were used as a basis for development of behaviour categories for this study.

Table 3.2.3.2a: Categories of behaviour (Kennedy, Fisher et al. 1988)

| SOLITARY BEHAVIOUR    |   |
|-----------------------|---|
| 1.                    | ISOLATED DISENGAGEMENT: Little external activity, physical isolation (eg sitting and gazing)  |
| 2.                    | INACTIVE INDIVIDUAL TASK: Activity not related to self care involving engagement with the environment (eg focused attention like watching tv) |
| 3.                    | ACTIVE INDIVIDUAL TASK: Solitary tasks involving gross motor skills (eg walking, exercises)   |
| 4.                    | INDEPENDENT SELF MAINTENANCE: Activity related to self care (eg eating, brushing teeth)   |
| 5.                    | DEVIAANT BEHAVIOUR: Obstruction to usual care (eg abusive or refusing treatment)  |
| INTERACTIVE BEHAVIOUR |   |
| 6.                    | INDIVIDUAL INTERACTION TASK: One-to-one communication associated with task activities   |
| 7.                    | INDIVIDUAL INTERACTION VERBAL: One-to-one communication associated with non-task activity (eg talking with roommate)                          |
| 8.                    | GROUP INTERACTION TASK: As 6 but involving more than 2 people   |
| 9.                    | GROUP INTERACTION VERBAL: As 7 but involving more than 2 people   |
| 10.                   | FORMAL MEETINGS: With family or carers  |

#### 3.2.3.3 Implementation of tool

Ward staff and AHPs at each of the trial facilities agreed to be observed with their patients during a 3-day pilot trial of behaviour mapping. The observer undertaking the mapping was a newly graduated physiotherapist.

Topographical and patient-based mapping were undertaken between 8.30am until 4.30pm over 3 consecutive days at each of the four ward facilities. The daily routine (Appendix 3) was consistent over the three days. Topographical mapping: For 15 minutes each hour, using a floor plan, the observer moved on a predetermined route through the ward and rehabilitation areas applying and recording the categories of behaviour to all ward patients. This provided a total of 60 observation sheets (15 at each facility) over 3 days. Within the general population, patients with stroke were identified and recorded.

#### Patient-based mapping:

The activity and location of four subjects with stroke was observed for 15 minutes in every hour. This provided a total of 192 observation sheets (48 at each facility) over 3 days. The information required to define the ward environment included what the activity was, whether it was solitary or interactive, and if task related, whether it was verbal or physical. In addition, during the 15 minutes of individual observation, the observer documented a description of the therapy undertaken, as described on the generic mapping form.

#### 3.2.3.4 Results of pilot study

Sixteen patients (4 at each facility) volunteered for the pilot study of the patient-based mapping, and provided informed written consent. The only selection criteria were that they were newly diagnosed with stroke, and were receiving some level of input from the AHPs. The daily routine was found to be appropriate and generated a useful number of maps at each facility. Familiarity with the individual ward's



protocols and routine made locating all patients trouble-free. All inpatients were located and accounted for over the 12 days.

The categories of behaviour were clearly defined and their application in topographical mapping was straightforward. Patients with stroke were easy to identify using the “Ps” notation. An example of a completed topographical map of the Swan Health Service GRU can be found in Appendix 3.

The patient-based mapping forms however were not easy to complete. If there was no therapy taking place, the location of the behaviour that was mapped was not documented. There was also a high level of detail required to adequately describe individual treatments, and the level of detail was inconsistent. In addition, the distinction between approaches was often unclear.

There was only one episode of “deviant behaviour” (during topographical mapping at Bentley) and only one formal meeting (during topographical mapping at SPC SU) over the 12 days of mapping. Neither episode involved patients with stroke.

Results suggest that the tool was able to demonstrate behaviour and location at the two types of facilities. Topographical mapping of both “All patients” (Figure 3.2.3.4a) and “Stroke patients-specific” (Figure 3.2.3.4b) demonstrated similar trends of frequency of each behaviour across all categories.

Mapping of all patients indicated that patients were more likely to be isolated at the GRUs (range 72.29 – 74.19%) compared with the SPC SU (59.37%). Stroke patient-specific results demonstrated a similar trend although the difference was less (restorative unit range 61.29 – 68.83%, SPC SU 57.02%). The higher rate of “Isolated Disengagement” at the GRUs (range 38.79 – 46.19% for topographical mapping) compared to SPC SU (20.11% for topographical mapping) accounted for the majority of this difference.

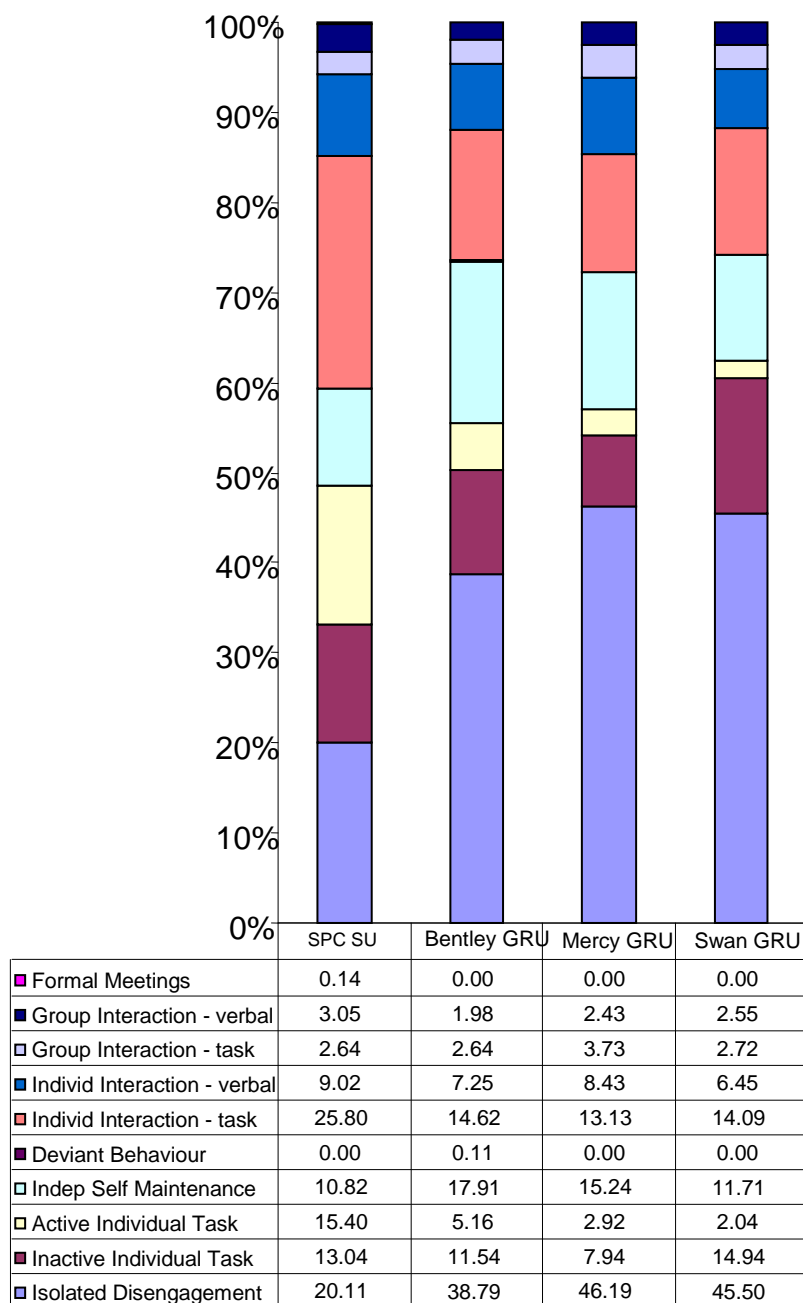


Figure 3.2.3.4a: Ward Mapping: Frequency of each behaviour (all patients)

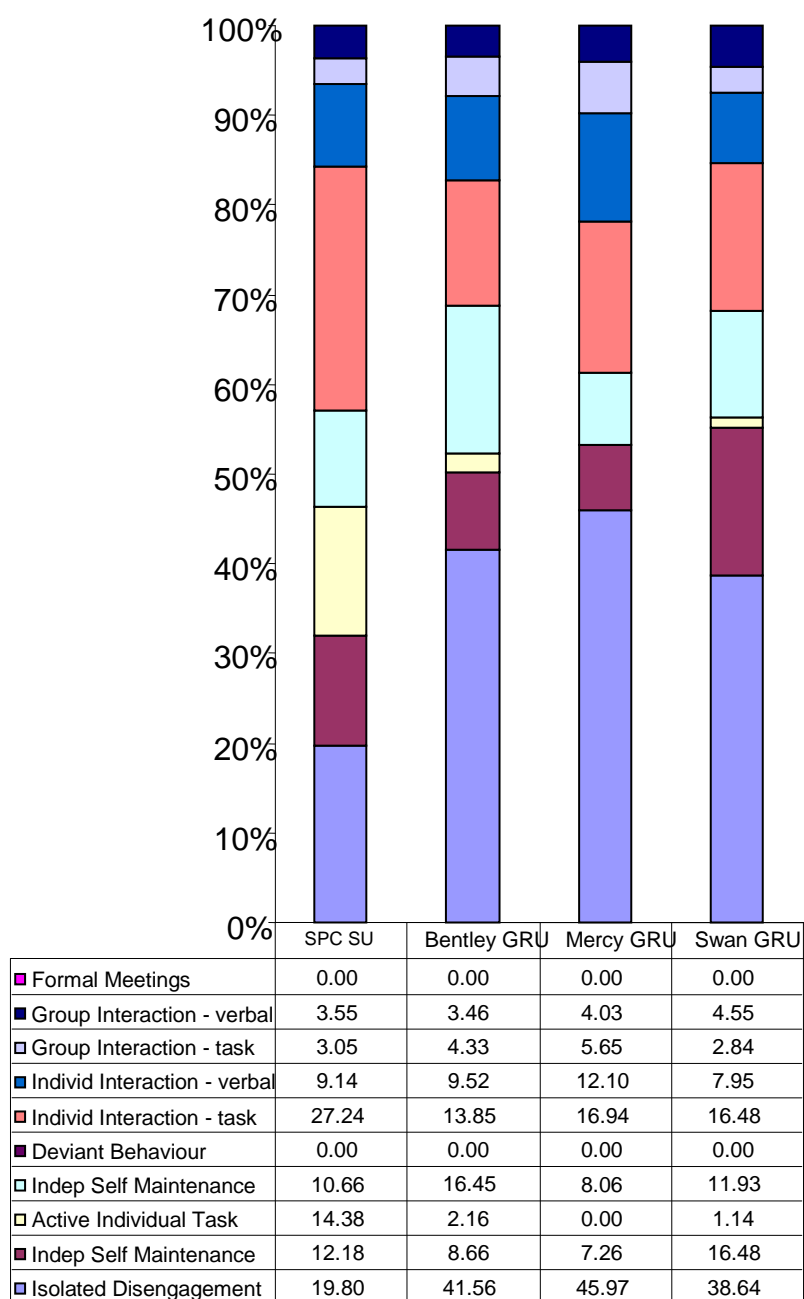


Figure 3.2.3.4b: Ward Mapping: Frequency of each behaviour (stroke patients)

There were a higher proportion of SPC SU patient observations involving individual interaction with a task compared with the other facilities (Whole ward mapping: GRU range 13.13 – 14.62%, SPC SU 25.8%; Stroke patient-specific results: GRU range 13.85 – 16.94%, SPC SU 27.24%).

Patient-based mapping: Frequency of each behaviour:

The patient-based mapping of stroke patients in terms of frequency of each behaviour demonstrated similar trends to those of the topographical mapping across all categories (Figure 3.2.3.4c).

Patients were more likely to be isolated at the GRUs (range 60.47-63.29%) compared with SPC SU (51.5%). The higher rate of “Isolated Disengagement” at the GRUs (range 32.56-40.20%) compared to SPC SU (8.33%) again accounted for the majority of this difference.

There was a difference in the proportion of patient observations that involved individual interaction with a task but this difference was less than during Whole ward mapping (GRU range 18.87-25.49 %, SPC SU 28.03%).

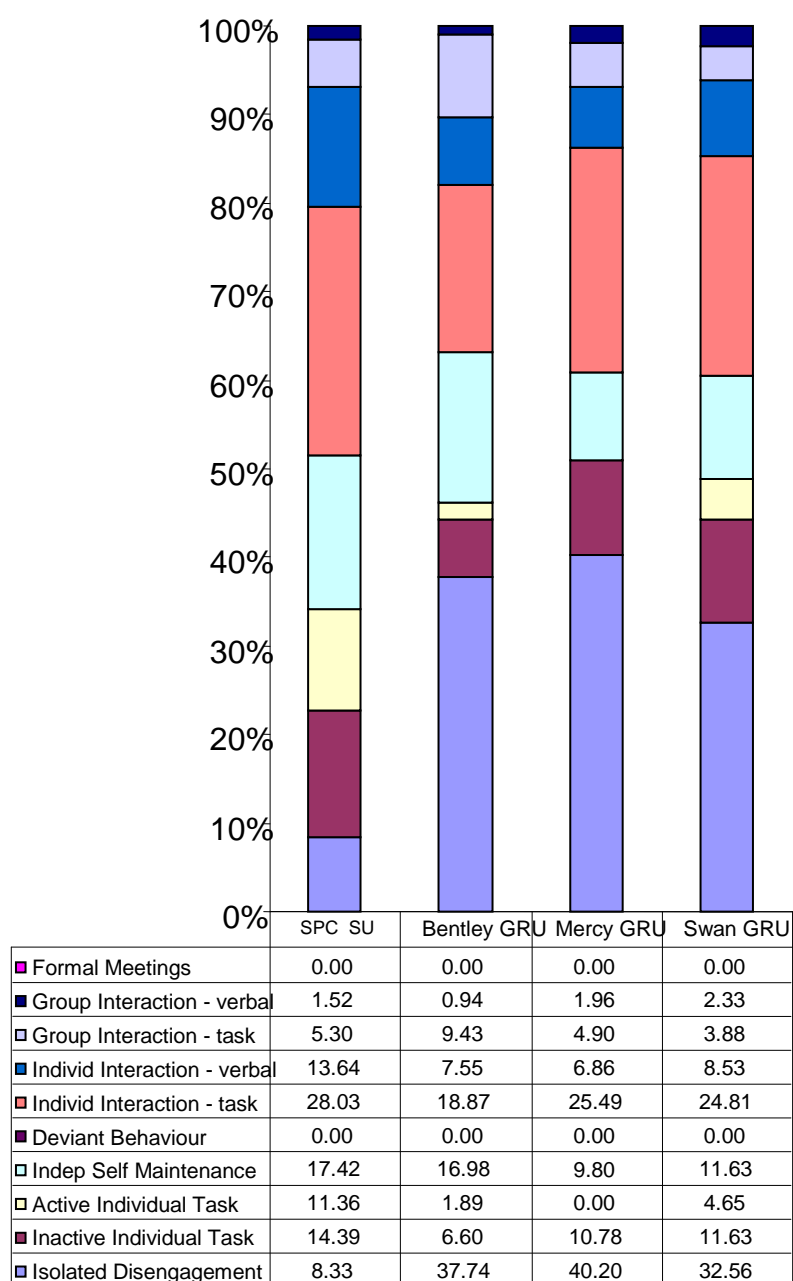


Figure 3.2.3.4c: Individual Mapping: Total frequency each behaviour

Patient-based mapping: Time observed each behaviour (Figure 3.2.3.4d):

The patient-based mapping of stroke patients in terms of the total observation time of each behaviour demonstrated similar trends as the frequency of each behaviour.

Patients were more likely to spend time isolated at the GRUs (range 61.57-64.09%) compared with the SPC SU (49.09%). The higher rate of “Isolated Disengagement” at the GRUs (range 36.56-42.31%) compared with SPC SU (6.67%) again accounted for the majority of this difference.

There was a difference in the proportion of time patients were observed in individual interaction with a task and this difference was comparable to the frequency of the patient-based observations cited previously (GRU range 14.35-23.43 %, SPC SU 27.73%).

Across both topographical and patient-based mapping, some categories of behaviour in Kennedy’s scale were not utilized, and as such provided no useful information regarding rehabilitation practices and the rehabilitation environment. Other categories were highly utilized.

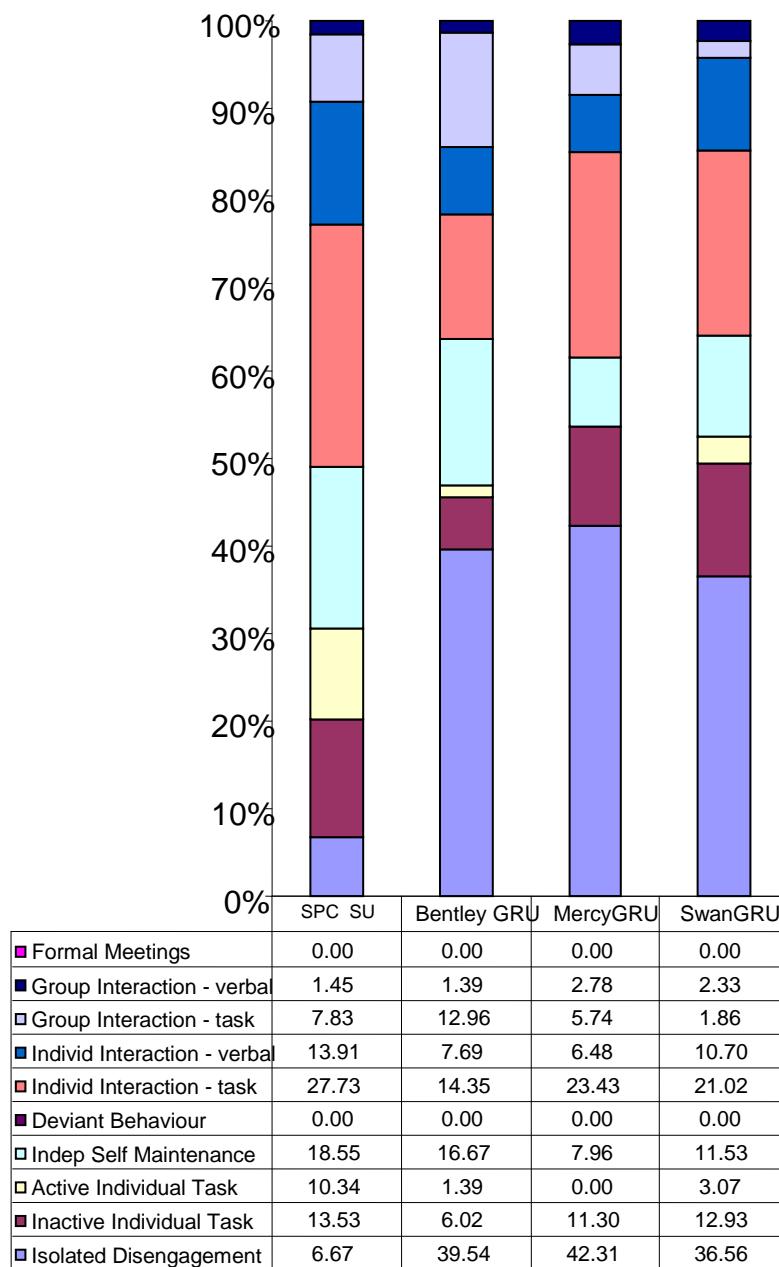


Figure 3.2.3.4d: Individual Mapping: Total time each behaviour

Topographical mapping: Location of patients (Figure 3.2.3.4e & 3.2.3.4f):

Patients at SPC SU were more likely to be in a therapy area during the day than in their rooms (284 out of 721 of all patient observations and 236 out of 591 of the total Stroke patient observations) than subjects at the GRUs (7/231 at Bentley, 13/124 at Mercy and 13/176 at Swan).

Patients at SPC SU were more likely to venture outside the hospital building (47 out of 721 of the total observations) than subjects at the GRUs (15 out of 910 of the total observations at Bentley, 20/617 at Mercy, and 0/589 at Swan). Observation of patients with stroke demonstrated the same trends (31 out of 591 of the total observations) than subjects at the GRUs (only 5 out of 124 of the total observations at Mercy, and 0 at the other units).

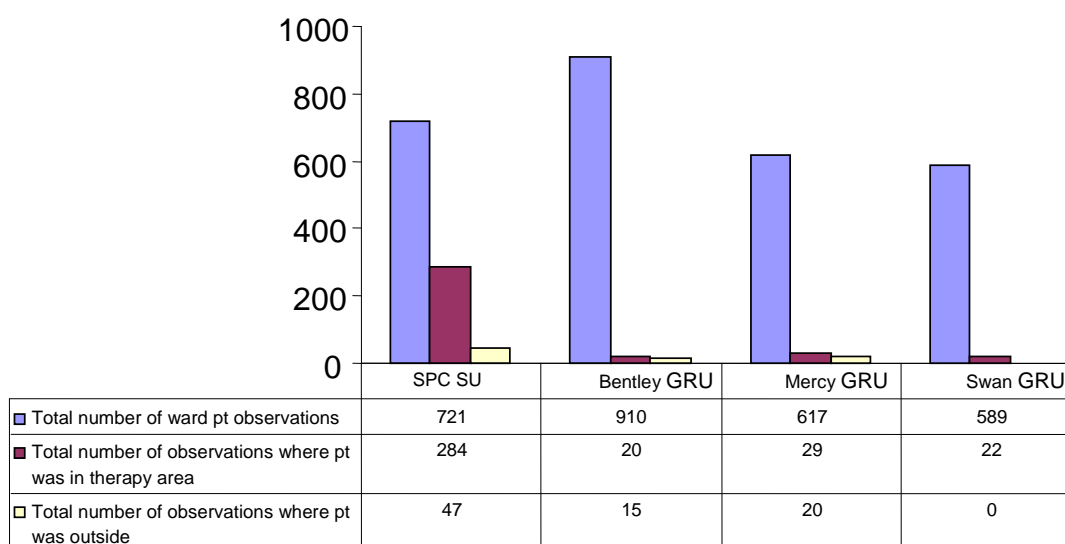


Figure 3.2.3.4e: Ward Mapping: Location (all patients)

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**



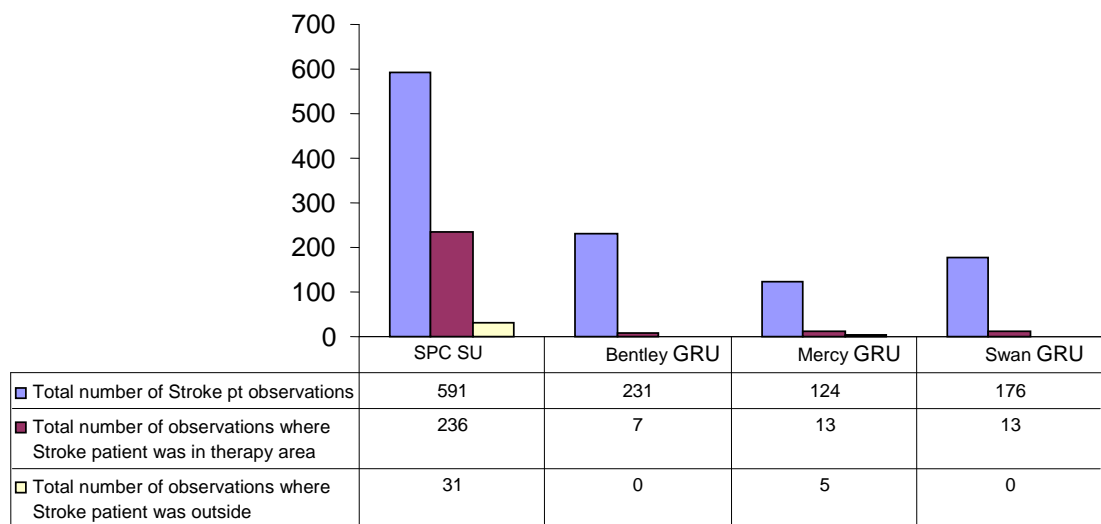


Figure 3.2.3.4f: Ward Mapping: Location (stroke patients)

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

Patient-based mapping: Location where behaviour was observed:

Other than if the patient was involved in therapy (a small number of observations overall and variable across sites), there were no data that qualified where behaviour was observed.

Topographical mapping: Empty patient room observations (Figure 3.2.3.4g): There were less occasions of empty rooms at Swan (27 out of 378 observations) compared with any of the other facilities.

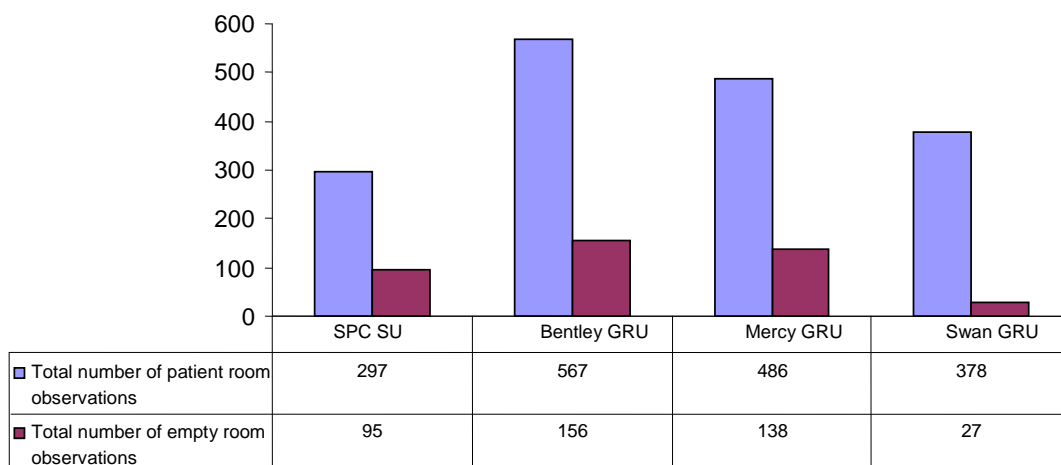


Figure 3.2.3.4g: Patient room observations

**SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional**

### 3.2.3.5 Implications for SRO study

The topographical maps were found to be useful in measuring the activity and location of the inpatients at each facility. The patient-based maps were useful in measuring the activity of the patients in terms of the category of the behaviour, but the descriptors of the behaviour had variable detail and covered too broad a range of activities to be useful. In addition, these descriptions had potential for observer bias based on the profession or qualification of the observer.

Following descriptive analysis of the data entered, some changes were made for the final SRO Trial behaviour mapping forms. The patient-based mapping sheets were simplified so the observer need only categorize the behaviour and account for the patient's location during the observation period (Appendix 12).

The categories of behaviour were redefined from a 10 to 15 point descriptive dichotomy that was more relevant for use in the observation of rehabilitating Stroke

patients (Table 3.2.3.5a). This redefinition involved the breakdown of categories having high frequency in pilot mapping and utilized descriptions of interaction provided from some of the completed individual maps to enable more meaningful conclusions from the results.

In the new dichotomy, “Solitary Behaviour” still contained 5 categories, however Kennedy’s category 1 (“Isolated Disengagement”) was broken down into 2 categories (1 and 2) according to whether the patient was in or out of bed whilst disengaged. Kennedy’s categories 2 – 4 were thus renumbered categories 3 – 5. Kennedy’s category 5 (“Deviant Behaviour”) was omitted.

It was difficult to classify some interactions as solitary or interactive as they appeared to be unique, and somewhere in between. These were therefore classed as “Mid-Interactive” and included “Independent activity in a Group environment” (new category 6) and “Being transferred between activities” (new category 7).

“Interactive Behaviour” contained a further 5 categories. Kennedy’s category 6 (“Individual Task”) was divided into 3 categories whereby category 10 related to visitors (“Individual or Group Task”), category 11 related to medical or nursing care (“Individual Task-medical or nursing”), and category 12 related to therapy (“Individual Task–therapy”). Kennedy’s category 7 (“Individual Verbal”) was divided into 2 categories whereby category 8 related to medical, nursing or therapy staff, and category 9 related to visitors. Kennedy’s categories 8 and 9 remained the same but were renumbered 13 and 14. Kennedy’s category 10 (“Formal Meetings”) was replaced with category 15 that described patient task orientated interaction in group setting.

Table 3.2.3.5a: Classification of patient behaviour to be used in SRO Trial

|  |
|--|
| <b>SOLITARY</b>  |
| 1 ISOLATED DISENGAGEMENT- PATIENT IN/ ON BED (e.g staring into space, asleep)  |
| 2 ISOLATED DISENGAGEMENT- PATIENT OUT OF BED (e.g staring into space, asleep)  |
| 3 INACTIVE INDIVIDUAL TASK (e.g watching television, reading)  |
| 4 ACTIVE INDIVIDUAL TASK (e.g. practicing exercises by themselves)   |
| 5 INDEPENDENT SELF MAINTENANCE (e.g. indep toileting, showering, self-care)  |
| <b>MID-INTERACTIVE</b>   |
| 6 INDEPENDENT ACTIVITY IN GROUP ENVIRONMENT  |
| 7 BEING TRANSFERRED BETWEEN ACTIVITIES BY STAFF  |
| <b>INTERACTIVE</b>   |
| 8 VERBAL INDIVIDUAL INTERACTION RELATING TO NURSING/MEDICAL/THERAPY  |
| 9 INDIVIDUAL OR GROUP INTERACTION THAT IS VERBAL ONLY AND RELATES TO SOCIAL VISITORS / FRIENDS (Also includes visitors who take patients out of the ward for a drink, etc if they remain non-ambulant)   |
| 10 INDIVIDUAL OR GROUP INTERACTION ASSOCIATED WITH TASK AND RELATES TO SOCIAL VISITORS / FRIENDS (Includes visitors who take patients out of the ward for a drink, etc if the patient ambulates)         |
| 11 INDIVIDUAL INTERACTION WITH TASK – RELATED TO MEDICAL/NURSING SELF CARE (e.g one nurse assisting with showering, toileting.)  |
| 12 INDIVIDUAL INTERACTION WITH TASK – RELATED TO THERAPY STAFF (e.g during treatment session with one AHP – includes shower assessments with OT)   |
| 13 AHP GROUP INTERACTION WITH TASK – RELATED TO THERAPY STAFF (e.g during treatment session with more than one AHP – where 2 or more therapy staff – including aides – are interacting with the patient) |
| 14 GROUP INTERACTION THAT IS VERBAL ONLY AND RELATES TO NURSING, MEDICAL OR THERAPY STAFF (e.g family meetings)  |
| 15 PATIENT GROUP INTERACTION WITH TASK – RELATED TO THERAPY STAFF (e.g group exercise class)   |
| <b>SRO=Stroke rehabilitation outcome</b>   |

Utilising the new behaviour categories outlined above, behaviour mapping was considered to be a valuable tool in measuring the differences between the four ward facilities. The main trial methodology was now ready to be developed, and will be outlined in the next chapter.

### 3.3 Conclusions from pilot studies

At the conclusion of these pilot studies, there was some evidence to suggest that there was a difference between the rehabilitative facilities. Specifically, visual examination of the descriptive results suggested that the 3 GRUs had more similar characteristics that were different to that of the SPC SU. Examples include the number of years qualification and the experience of treating patients with stroke, the level of continuing education, the treatment philosophies and the number of patients with stroke seen daily (AHP questionnaire data); the amount of time spent undertaking treatment versus administration, and individual versus group therapy (patient diary data); and the patient's location and activity (behaviour mapping data). Although the sample sizes used in the pilot data were too small to generate meaningful results, they supported the premise that the GRUs were more similar than different, and could therefore be grouped together for analyses in the main study.

These pilot studies also provided 2 tools that had been considerably tested, revised and developed for use in the main study. All SRO patients would subsequently carry rehabilitation diaries for the duration of their inpatient rehabilitation stay, and regular ward and SRO subject behaviour mapping would be carried out at each facility, using the newly developed maps and classification of behaviours.



## CHAPTER 4

### Literature Review of Outcome Methods

#### 4.1 Introduction

Baseline data were used to determine if patients undergoing rehabilitation at the two different types of facility were significantly different. Data pertaining to inpatient sub-acute rehabilitation were recorded in order to determine whether or not there was a direct relationship between the amount of allied health input and the length of stay, and the level of functional outcome at different facilities. They also enabled a global measure of comparative cost analysis between groups. Post-rehabilitation data were collected at 6 and 12 months to measure functional ability and quality of life at these time points.

#### 4.2 Baseline measures

##### 4.2.1 Age

Chronological age is routinely recorded on acute hospital admission. In rehabilitation it is often assumed that younger patients will make faster and more significant functional gains compared with their older counterparts, however there is inconclusive evidence on the influence that age has on the potential for recovery and positive outcome in stroke rehabilitation. Studies have found that increasing age is associated with higher death rate (Kammersgaard, Jørgensen et al. 2004; Calmels, Defay et al. 2005) but not poorer outcome (Calmels, Defay et al. 2005), no difference in outcome (Bagg, Pombo et al. 2002) or poorer outcome (Granger, Hamilton et al. 1992; Black-Schaffer, Winston et al. 2004; Kammersgaard, Jørgensen et al. 2004). Studies have also purported age as an important clinical determinant of the quality and quantity of stroke care provided (Palnum KD, Petersen P et al. 2008; Luker, Wall et al. 2011). In order to rule out age at baseline as a confounding factor in the

present study, the age data for both groups was collected and compared to ensure that the SU and GRU cohorts were similar, or if dissimilar used as covariates.

#### 4.2.2 Barthel Index (BI)

##### Development, indication and description

This tool was developed for use in rehabilitation patients with stroke and other neuromuscular or musculoskeletal disorders (Mahoney 1965). It measures the extent to which somebody can function independently in their activities of daily living (ADL) and thereby the need for assistance in care. It is now frequently used in stroke research to determine the extent of post-stroke disability, self-care activities and ability to live independently. It has also been found to predict length of stay in hospital (Granger, Albrecht et al. 1979).

The 10-item form of the BI addresses 10 common ADL activities: feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing. Items are rated in terms of whether individuals can perform activities independently, with some assistance, or are dependent (scored as 10, 5, or 0 respectively). The score of the BI is a summed aggregate and yields a total score out of 100 - the higher the score, the greater the degree of functional independence (Appendix 14).

##### Reliability and validity

Since first published (Mahoney 1965), the tool has shown to be a reliable and valid measure of basic ADL (Hsueh, Lee et al. 2001; Leung, Chan et al. 2007). A common criticism is the limited range of disability within which it is able to detect change. In their study of 90 Spanish stroke survivors, Carod-Artal et al found the measure demonstrated a ceiling effect, as it was insensitive to subjective dysfunction in patients with high level of ADL performance (Carod-Artal, Egido et al. 2000). This suggests that the BI is not sensitive to change among the least impaired stroke survivors. However, an earlier study concluded that while the BI may not be able to



detect change within an individual who is independent, it is able to detect when a patient requires assistance (Wade and Collin 1988).

#### Clinically relevant cut-off scores

A recent study of patients with stroke defined good or bad outcome, as BI  $\geq$  95 or  $<$  95 respectively (Berge, Fjaertoft et al. 2001).

#### Justification

It was decided to use the measure to identify potential differences between groups at baseline in terms of the level of dependency. Although the ceiling effect in the BI is well documented (Carod-Artal, Egido et al. 2000), it was thought that it would be irrelevant at that time point, because the level of function would most likely be low in view of the need for ongoing rehabilitation (and thereby inclusion in the trial). At 6 and 12-month follow-up, when the patient had the potential to be at a higher functional level, a more sensitive measure of ADL was required and used (see 4.4.6 FIM). Importantly, the literature has demonstrated good construct validity between the two measures (Gosman-Hedstrom and Svensson 2000).

#### 4.2.3 Mini-Mental State Examination (MMSE)

##### Development, indication, description, reliability and validity

The Mini-Mental State Examination (MMSE) is a well-validated observer-related measure of cognitive ability, designed originally to screen for dementia in the elderly and now widely used across all settings. (Folstein, Folstein et al. 1975). It is used to detect the presence of cognitive impairment, rather than provide a diagnosis, and has been used extensively in patients with stroke (Grace, Nadler et al. 1995; Suhr and Grace 1999; Agrell and Dehlin 2000; Ozdemir, Birtane et al. 2001). The MMSE is not used to measure changes over time, as a reduction in its validity has been shown with repeated measures over a short time period (Folstein, Robins et al. 1983).

It consists of 11 simple questions or tasks that look at various functions including: arithmetic, memory and orientation (Appendix 21). The score is the number of correct items with a total possible score of 30, and a lower score indicating greater impairment in cognition (Folstein, Folstein et al. 1975).

#### Clinically relevant cut-off scores

Since 1993, the MMSE has been available with an attached table that enables patient-specific norms to be identified on the basis of age and educational level (Crum, Anthony et al. 1993). Serious cognitive function was defined as a score lower than 17 (Folstein, Folstein et al. 1975).

#### Justification

It has been shown that higher-order cognitive impairments (comprehension, judgment, short-term verbal memory, and abstract thinking) are important factors in extending length of stay and increasing referrals for outpatient therapies and home services after discharge for stroke (Galski, Bruno et al. 1993). In order to rule out differences in cognitive levels at baseline as a confounding factor in the present study, the MMSE data from both groups were collected and compared to ensure that the SU and GRU cohorts were similar on this factor.

#### 4.2.4 Rankin Scale

##### Development, indication, description, reliability and validity

The Rankin scale is an observer-rated global measure of performance in ADL assessing handicap and any limitation in the patient's social role on a scale of 0 – 5 (Rankin 1957) (Appendix 23). It should be viewed as a global functional health index with a strong accent on physical disability (de Haan, Limburg et al. 1995). A score of 0 reflects no handicap and 5 reflects severe handicap, whereby the individual is totally dependent, requiring constant attention, day and night (Bamford, Sandercock et al. 1989). The index is useful as a simple and time-efficient tool, and has shown acceptable inter-observer reliability (van Swieten, Koudstaal et al. 1988).

## Justification

The Rankin score was used to provide a global measure of ADL in order to rule out differences in functional levels at baseline as a confounding factor in the present study. Data from both groups were collected and compared to ensure that the SU and GRU cohorts were similar.

### 4.2.5 Scandinavian Stroke Score (SSS)

Development, indication, description, reliability and validity

This is a prognostic score that was developed by the Scandinavian Stroke Group (Scandinavian 1985) in the absence of any available scoring systems for use by non-neurologists (Appendix 24). The group conducted a multi-centred trial looking into haemodilution in acute ischaemic stroke, and used the score to further stratify treatment groups (choosing initial prognostic score ranges of 0-15 points and 16-22 points) across patients already stratified for age. The initial prognostic score (range 0-22 total) includes level of consciousness, eye movements and severity of paresis whereby the higher the score, the higher function and better prognosis.

The long term functional score (range 0-48 total) focuses on items easy to assess and of functional significance to the patient. These include orientation and speech and strength of facial muscles, limbs and gait independence. As with the initial score, the higher the long term score, the higher the function and better prognosis.

During the haemodilution trial (Scandinavian 1985; Scandinavian 1987; Scandinavian 1988) the long term functional score was performed on day 1 and 6 and at 3 months. The study group reported high validity of the scoring system, as initial scoring strongly predicted mortality and function at 3 months in stroke survivors (Scandinavian 1987; Scandinavian 1988).

## Justification

In the present study, the SSS was used to provide a global measure of prognosis and function in order to rule out differences between the two groups at baseline. Data from both groups were collected and compared to ensure that the SU and GRU cohorts were similar.

## 4.3 Rehabilitation measures

### 4.3.1 Patient diary

Development, indication and description; Reliability and validity; Justification

See Chapter 2: Pilot Studies

## Justification

Patient diaries were used in order to observe if there were any differences between the length and frequency of patient treatment by allied health staff at SPC SU, compared with three GRUs.

### 4.3.2 Hospital length of stay (LOS)

Development, indication, description, reliability and validity

Hospital length of stay (LOS) is routinely recorded on discharge. There are a number of indications for collecting LOS data. It may be used in cost analysis as the proxy for resource use because of its high correlation with charges and its freedom from distortion due to the labor market and local cost factors (Heinemann, Linacre et al. 1994). It may also be used as a time point where level of functional gain is defined, as significant gains in functional independence prior to acute hospital discharge are more and more difficult to achieve (Bohannon 2003) and different rates of functional improvement in stroke have been found to directly relate to length of hospital stay (Alexander 1994).

## Justification

Basic allied health professional statistics pertaining to the duration of interventions as well as hospital LOS data were collected for both groups and compared in order to detect a significant difference between groups both in terms of therapy input and acute hospital and rehabilitation hospital LOS.

### 4.4 Patient measures

#### 4.4.1 Action Research Arm Test (ARAT)

##### Development, indication and description

The ARAT (Appendix 13) is an upper limb-specific measure of activity limitation assessing the individual's ability to manipulate both small and large quantifiable objects (Lyle 1981). It is based on the upper extremity function test (Carroll 1965) and was constructed for assessing the recovery of upper extremity function (focal disability) following cortical injury (Hsueh, Hsieh et al. 2002). It assesses the ability to handle objects differing in size, weight and shape and therefore is considered to be an arm-specific measure of activity limitation (Platz, Pinkowski et al. 2005). It is one of the most common outcome measure used to assess upper limb function in cortically injured patients with upper limb paresis (Platz, Pinkowski et al. 2005). The ARAT has been used as the primary outcome measure in several studies (Kwakkel, Wagenaar et al. 1999; Parry, Lincoln et al. 1999; van der Lee, Wagenaar et al. 1999).

The tool includes 19 items and contains four subscales: 'grasp', 'grip', 'pinch and 'gross movement'. The items are graded on a four-point scale (whereby 0 = cannot perform any part of the test; 1 = performs the test partially; 2 = completes the test, but takes abnormally long, time and 3 = performs the test normally). If a patient accomplishes the most difficult item (scoring 3), this predicts success with all less difficult subscale items and the patient is credited with succeeding with all items of the subtest for that limb (all scoring 3). If the patient is unable to complete the most difficult item (scoring between 0-2), then the easiest item in this specific subscale

should be performed. If the patient fails completely (score = 0) when performing the easiest task, then the other intermediate items are not tested, the entire subscale should be scored as zero, and the evaluator should then move to the next subscale. However, if the client succeeds at the easiest task either partially (score = 1 or 2) or completely (score = 3), then all the other tasks in that same subscale should be tested before moving to the next subscale. Correspondingly, scores will range between 4 and 19. The scores on the different items are added together, with a possible range of 0 (no movements can be performed) to 57 (normal performance).

The following equipment is required: a chair and table, wooden blocks, a cricket ball, a sharpening stone, two different sizes of alloy tubes, a washer and bolt, two glasses, a marble and a 6-mm ball bearing. It takes no more than 10 min to examine a stroke patient on the ARAT.

#### Reliability and validity

Many studies have demonstrated high reliability and validity for the ARAT. Most recently, intra-rater reliability was shown to be excellent for the total score (ICC = 0.99 and  $\rho = 0.99$ ) and across all subscales (grasp ICC = 0.98 and  $\rho = 0.93$ ; grip ICC = 0.97 and  $\rho = 0.93$ ; pinch ICC = 0.99 and  $\rho = 0.98$ ; and gross motor ICC = 0.93 and  $\rho = 0.91$ ) (Yozbatiran, Der-Yeghiaian et al. 2008).

Inter-rater reliability has been also shown to be excellent (van der Lee, deGroot et al. 2001; Yozbatiran, Der-Yeghiaian et al. 2008), as has test-retest reliability for both the total and sub-scores (Platz, Pinkowski et al. 2005).

The ARAT has been found to be responsive to change (Lang, Wagner et al. 2006), with effect sizes greater than 1.0 for both total and sub-scores, and responsiveness ratios of 7.0 at 3 months post-stroke. This suggests that the ARAT is a sensitive tool for detecting change even months after stroke onset. This study also evaluated the convergent validity of the ARAT compared to measures of sensorimotor impairment

(e.g. light touch sensation, pain, elbow joint spasticity, upper extremity strength), to kinematic measures (e.g. reach and grasp), to the Functional Independence Measure (FIM), and to the National Institutes of Health Stroke Scale (NIHSS). At all 3 time points, ARAT scores related to comparative measures, and the ARAT was therefore found to be a valid measure of upper extremity functional limitation post-stroke.

#### Clinically significant difference

The ARAT scores is a continuous measure, with no categorical cutoff scores. Therefore the score obtained at the ARAT does not allow classifying scores into categories such as normal, mild limited, or severely limited. There are published normative values available for stroke patients (Kwakkel, Wagenaar et al. 1999; Parry, Lincoln et al. 1999; van der Lee, Wagenaar et al. 1999), and a 10% difference in total score represents a minimally important clinical difference (van der Lee, Beckerman et al. 2001; van der Lee, Leo et al. 2002).

#### Justification

Up to fifty percent of stroke patients who experience initial upper limb impairment post-stroke will still have impairment up to four years on (Broeks, Lankhorst et al. 1999), and the management of this pain is multidimensional (Zeferino and Aycock 2010). The ARAT is designed for evaluation of both sides of patients with cortical injuries, helping to obtain a more total description of the upper extremity function than investigation of only the hemiplegic side. From the point of view of dependency it is necessary to know whether the patient has unlimited function on the non-affected side (Hsieh, Hsueh et al. 1998). It is quick and easy to use and assesses both proximal and distal strength as well as dexterity. This makes it preferable to other tools such as the nine-hole peg test (finger dexterity) or grip strength (distal strength) that focus on only one component of arm-hand function.

#### 4.4.2 Behaviour Mapping

Development, indication and description; Reliability and validity

See Chapter 2: Pilot Studies

##### Justification

Behaviour mapping was used in order to observe if there were any differences between where and how patients with stroke spent their time in a SU, compared with three GRUs.

#### 4.4.3 Berg Balance Scale (BBS)

Development, indication and description

This scale was originally developed for older adults as a measure of dynamic balance performance (Smith, Hembree et al. 2004) through a process that used interviews with rehabilitation professionals and individuals with balance deficits to generate a pool of 38 balance items. Items were then excluded systematically on the basis of perceived usefulness and clarity, consideration of the internal consistency and examination of reliability, until 14 tasks remained (Berg, Wood-Dauphinee et al. 1989).

Since the introduction of the tool in the early 1990's the BBS has been used for a variety of functions, including an evaluative manner in projects examining the effectiveness of different interventions (Stevenson 2001). The multiple-item format of the assessment provides the clinician with additional insight into the possible aetiology for the balance disturbance (Smith, Hembree et al. 2004) including the ability to tolerate the internally produced perturbation to standing balance associated with forward arm flexion (Stevenson, Garland et al. 1996) and its use for the assessment of standing balance in subjects with hemiparesis from stroke is therefore supported (Appendix 15).



Used widely by physiotherapists, this series of 14 static and dynamic observable balance tasks is scored on a 5-point ordinal scale (0-4) according to the quality of performance, the time taken to complete the skill or maintain a specific posture (Smith, Hembree et al. 2004). Scores therefore may range from 0-56 with 56 being the maximal score possible. Equipment requirements include a chair with and without arms, a 15cm stepstool, a 30cm ruler, a stopwatch, and a slipper.

#### Reliability and validity

The initial examination of reliability resulted in a calculated inter-rater ICC=0.98 and intra-rater ICC=0.97 for the total BBS score (Berg, Wood-Dauphinee et al. 1989). Studies have also shown excellent internal consistency and both inter-rater and intra-rater reliability (Berg, Wood-Dauphinee et al. 1995) in elderly stroke patients. It is also sensitive to change (Salbach, Mayo et al. 2001; English, Hillier et al. 2006) and demonstrates large effect size (English, Hillier et al. 2006). In terms of validity, it has been found to correlate with the Barthel Index and the balance subscale of the Fugl-Meyer and the Timed Up and Go Test (Berg, Wood-Dauphinee et al. 1992), and the Functional Independence measure (Wee, Bagg et al. 1999).

#### Minimal detectable and clinically significant difference

In a study of 48 subjects receiving inpatient rehabilitation after stroke, the minimal detectable change score analysis suggested that a change of  $\pm 6$  BBS points is necessary to be 90% confident of genuine change (Stevenson 2001). A score greater than 45 is clinically associated with a lower risk of falling (Berg, Wood-Dauphinee et al. 1992), and normative values have been published (English, Hillier et al. 2006).

#### Justification

Impaired balance is a common characteristic of patients with stroke, secondary to neurological impairment in strength and tone and/or the co-ordination of both fine and gross movement that may be compounded by the effect of increasing age (Winter, Patla et al. 1990). Sensory impairment (both central and peripheral) may

also result in balance disturbance. Because the BBS is a sensitive and valid measure of balance that has been widely published, it was chosen in order to identify differences in outcome between the two types of facilities.

#### 4.4.4 Chedoke-McMaster Postural Control & Shoulder Impairment Scores

##### Development, indication and description

The Chedoke-McMaster Stroke Assessment is a performance-based measure that consists of two inventories: the Impairment Inventory and the Activity Inventory. It consists of specific tasks that classify the stage of motor control (1-7) across all 6 areas of function from limb movement to trunk control and shoulder pain (Appendices 16 and 17).

This scale is utilised as both a clinical and a research tool that can discriminate among subjects and evaluate patient outcomes. The measure has three overall purposes: 1) to stage motor recovery to classify individuals in terms of clinical characteristics, 2) to predict rehabilitation outcomes, and 3) to measure clinically important change in physical function (Gowland, Stratford et al. 1993).

The minimum score for the overall Impairment Inventory is therefore 6 and the maximum score is 42 (Gowland, Stratford et al. 1993). In addition, each area of assessment has been independently validated. The 7-point scale for shoulder pain is based on pain severity and 7-point scale for postural control defines recovery over 7 stages (Stage 1 relating to poor function and stage 7 relating to normal function). The scale is predicated on the knowledge that motor recovery progresses in discrete phases that reflect the degree of neurological impairment and recovery (Gowland, Stratford et al. 1993).

##### Reliability and validity

The Chedoke-McMaster Stroke Assessment yields both reliable and valid results. In a study of 32 subjects from a stroke rehabilitation unit, Gowland et al (1993)

assessed the intra-rater, inter-rater, and test-retest reliabilities of the impairment and disability inventories of the Chedoke-McMaster Stroke Assessment. Reliability coefficients for the total scores ranged from 0.97 to 0.99. Construct and concurrent validities were studied by examining the correlations between this and other measures. Correlations were found to be greater than 0.60, with the impairment inventory total score was found to correlate with the Fugl-Meyer Test ( $r = 0.95$ ,  $p < 0.001$ ) and the disability inventory with the FIM ( $r = 0.79$ ,  $p < 0.05$ ) (Gowland, Stratford et al. 1993).

#### Justification

Both the shoulder subscale score and the postural control subscale scores were chosen in view of the fact that these domains were not covered in any other chosen outcome measures and are accepted as a common clinical focus in the rehabilitation of stroke patients.

#### 4.4.5 European Quality of Life-5 Dimension visual analogue scale (EQ5D VAS)

##### Development, indication and description

This tool measures health-related quality of life (HRQoL) and was developed and validated in Europe (EuroQol 1990). It describes health status according to five dimensions: mobility, self-care, usual activities, pain/ discomfort and anxiety/depression. Each dimension has three levels, namely, "no problems", "some problems" and "severe problems". This yields 243 potential combinations of health states across the five dimensions. Besides the five dimensions, the EQ-5D consists of a visual analogue scale (EQ5D VAS) ranging from 0 (worst imaginable health state) to 100 (best imaginable health state).

It is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care. One limitation is that it could

be insensitive to changes that are considered clinically or socially significant, therefore it is not the focus of the economic analysis.

#### Interpreting data

Data can be presented in various ways. The digits for 5 dimensions can be combined in a 5- digit number describing the respondent's health state (the numerals 1-3 have no arithmetic properties and should not be used as a cardinal score, and a total of 243 unique health states may be defined in this way); the EQ VAS may be reported as an overall self-rated health status; or results from the descriptive system may be presented as a weighted index.

#### Justification

The EQ5D VAS (Appendix 18) was chosen for the present study in order to identify differences in outcome between the two types of facilities as it was cognitively undemanding and took only a few minutes to complete.

#### 4.4.6 Functional Independence Measure (FIM)

##### Development, indication and description

The FIM (Appendix 19) was originally developed by a national taskforce following a recommendation in 1984 from the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation (Keith, Granger et al. 1987), and is part of the Uniform Data System for Medical Rehabilitation (UDS) which also contains demographic, diagnostic, impairment groups, length of hospital inpatient stay and cost information (Fricke 1993); (Heinemann, Linacre et al. 1993).

The scale consists of 18 items each assessed on 7 levels which, when summed, may be used to estimate a person's need for assistance (burden of care) or resource cost of disability. The scale is anchored by extreme ratings of total assistance (1) and complete independence (7), and considers extent of assistance, supervision, and use

of adaptive equipment (Heinemann, Linacre et al. 1993). Possible scores range from 18 to 126. In addition to a total score, the FIM provides two domain scores (motor and cognitive), six subscale scores (self-care, sphincter control, transfers, locomotion, communication and social cognition), and 18 individual item scores (Guide87). It does not include domestic or community ADL (Fricke 1993).

Though each FIM item contributes its own, unique information, it is impractical clinically, and burdensome analytically to allow each item to act as a separate measurement device. The FIM was intended to quantify one unambiguous disability indicator by combining its 18 items to yield a summary score.

#### Reliability and validity

The FIM has demonstrated no ceiling effect when compared with other measures (van der Putten, Hobart et al. 1999) and is sensitive to change (Dromerick, Dorothy et al. 2003) and has acceptable levels of reliability (Ottenbacher, Hsu et al. 1996, Fricke, 1993 #433, Granger, 1990 #456); and validity (Dodds 1993; Kelly, Furie et al. 2003). It has also demonstrated construct validity with the BI (Gosman-Hedstrom and Svensson 2000).

#### Indications for using tool

The FIM represents the “burden of care” for the care provider, whether the provider be spouse, family or institution (Granger and Hamilton 1990). It is designed for use by any discipline, is suitable for a wide range of diagnoses (Fricke 1993) and gives rehabilitation providers a common language with which to discuss disability in terms of functional activities or activities of daily living (Black, Soltis et al. 1999). Although it does not measure more specific functional skills, such as fine motor ability, speed, and ease of task completion, or quality of task execution (Dodds 1993), as a generic assessment tool, it may serve several purposes, ranging from outcomes research to program evaluation. Scores from the FIM are commonly used

to predict and demonstrate rehabilitation success (Sandstrom, Mokler et al. 1998);(Oczkowski, Barreca et al. 1993).

#### Clinically significant differences

While no recommendations exist for what constitutes a clinically significant change on the FIM, a 10-point improvement in raw score decreases by almost 50 percent the time required to care for a group of stroke patients in the community (Granger, Cotter et al. 1993).

Admission FIM scores of less than 40 have been associated with less change in FIM score over time, high level of impairment and disability, and heavy “burden of care” necessitating institutionalization on discharge (Ween, Alexander et al. 1996, Oczkowski, 1993). At the other end of the spectrum, stroke patients with an admission FIM greater than 80 almost universally are discharged to their own home (Black, Soltis et al. 1999). An admission FIM of 60 or more was associated with a higher probability of functional improvement during rehabilitation. (Ween, Alexander et al. 1996). Admission FIM scores above 96 have also demonstrated little change over time (perhaps relating to a ceiling effect), and correspondingly low levels of impairment and disability, and discharge to home (Oczkowski, Barreca et al. 1993). Overall, those mid-range patients with admission FIM scores between 36 and 96 changed the most in their FIM scores, had moderate impairment and disability, and destination on discharge was more difficult to predict (Oczkowski, Barreca et al. 1993). It may be important to consider that age has shown a significant but small effect on functional outcome when outcome is measured as FIM score (Bagg, Pombo et al. 2002).

#### Justification

A measure of ADL was needed, as they have been found to be more useful in treatment trials (Dromerick, Dorothy et al. 2003) due to their sensitivity to change in disability compared with other global measures of health. The FIM was chosen as

the primary measure to assess differences in functional outcome between the two different types of facilities in the SRO study, as a sensitive, inclusive, (Granger, Cotter et al. 1993) and responsive ADL measure.

#### 4.4.7 Hospital Anxiety and Depression Scale (HADS)

##### Description and development of tool

The Hospital Anxiety and Depression Scale (HADS) was specifically designed to be a brief self-assessment tool for use in patients with somatic co-morbidity, and limited to the two most common aspects of neurosis presenting in hospital practice: anxiety and depression (Zigmond and Snaith 1983). It takes only 2 to 5 minutes to complete, and consists of 7-item subscales for both depression and anxiety (Aben, Frans et al. 2002). Items were selected based solely on the psychic symptoms of neurosis rather than emotional or physical disorders (Zigmond and Snaith 1983) such that symptoms such as dizziness, headaches, insomnia and fatigue were excluded as well as those relating to serious mental disorders (Bjelland, Dahl et al. 2002). Each item has a 4-point response category (0-3) so that the possible scores range from 0-21 for anxiety and 0-21 for depression (Appendix 20).

##### Reliability and Sensitivity of tool

The tool has demonstrated excellent internal consistency and sensitivity (Olsson, Mykletun et al. 2005, Aben, 2002, Zigmond, 1983) and validity has been well established across different countries and disorders (Snaith 2003).

##### Indications for using tool

The HADS was specifically designed to facilitate the large task of detection and management of psychiatric disorders in patients under investigation and treatment in medical and surgical departments (Zigmond and Snaith 1983). A review of the literature in 2002 identified 747 papers that had used HADS to address research questions. Overall it was found to perform well in assessing the symptom severity and the presence of anxiety disorders and depression in both somatic, psychiatric and

primary care patients and in the general population (Bjelland, Dahl et al. 2002). Specifically in patients with stroke, the total HADS score is accurate in detecting cases of post-stroke depression (Aben, Frans et al. 2002).

The internal consistency of the scale was high, and only slightly decreased in a subset of patients with low MMSE scores ( $\leq 23$ ). In this group, non-response was clearly higher. This suggests that, overall, stroke patients are able to fill out these scales reliably, but problems arise in the more cognitively impaired patients (Aben, Frans et al. 2002).

#### Clinical thresholds

For the depression subscale, a score of 7 or less for non-cases, 8-10 for doubtful cases and 11 or more for definite cases; for the anxiety subscale, the same score ranges fit (Zigmond and Snaith 1983). Aben et al (2002) found that the optimal cutoff point for the depression subscale was a score of 8 (sensitivity: 73.1, specificity: 81.6), and the anxiety subscale was a score of 5 (sensitivity: 91.7, specificity: 56.1) (Aben, Frans et al. 2002). Screening for both major and minor depression did not change the overall accuracy of the instrument, however the optimum cutoff score decreased by one point to 7 on the depression subscale (Aben, Frans et al. 2002). Olssen (2005) replicated these optimal cut off scores in a general practice caseload with sensitivity 0.89, specificity .75 for anxiety and sensitivity 0.80 and specificity 0.88 for depression (Olsson, Mykletun et al. 2005).

The scores on the subscales are indicators of the severity of the depression and anxiety respectively ( $r=0.70$  and  $r=0.74$ ) with  $p<0.001$ . The subscales are thought to assess different aspects of mood disorder (Zigmond and Snaith 1983),

#### Justification of choice of outcome measure

The HADS is a widely used screening tool in medically ill patients (Tang, Wong et al. 2007) and seems to have at least as good screening properties as similar more



comprehensive instruments used to identify anxiety and depression (Bjelland, Dahl et al. 2002). Although the SRO study cohort was medically stable, because it is a simple to use and is well validated in stroke, often demonstrating the presence of significant anxiety and depression within this cohort (Robinson, Starr et al. 1984; Robinson, Bolduc et al. 1987; Astrom 1996), it was deemed suitable for study.

#### 4.4.8 MOS 36-Item Short Form Health Survey (SF-36)

##### Description and development of tool

The SF-36 (Appendix 22) is the most widely used generic instrument for measuring quality of life (de Haan 2002) and for which Australian normative data are available (McCallum 1995). It provides a comprehensive, psychometrically sound, and efficient way to measure health from a patient's point of view by scoring standardized responses to standardized questions.

The SF-36 comprises eight health scales: physical functioning (10 items), role limitations – physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social functioning (2 items), role limitations – emotional (3 items), and mental health (5 items). Two core dimensions of health, physical and mental can be derived from these eight scales. There is also a single separate item that is used to assess any change in health from 1 year before (Anderson, Laubscher et al. 1996).

##### Reliability and Sensitivity of tool

The tool has been translated into numerous languages, and the validity of the 8 subscales is confirmed in general populations and in a wide variety of patient groups in more than 2000 articles including stroke (McCallum 1995, Brazier, 1992; de Haan 2002). Moreover, when compared to the ceiling effect of the BI, the physical functioning scale of the SF-36 showed a uniform distribution of scores that reflected a broader range of physical disability (Anderson, Laubscher et al. 1996).

### Indications for using tool

The focus of the SF-36 is on the subjective perception of health (Carod-Artal, Egido et al. 2000). This is in the context that isolated measures of physical health domains may not adequately reflect the full impact of the long-term disability in stroke that a quality of life measurement may provide. These additional subjective components show the effect of survivor attitudes, health beliefs, and social interaction.

### Normative values and clinically significant difference for patients with stroke

Compared to the general population, overall quality of life outcomes reported for patients with stroke vary. A Scottish study reporting on a large sample of mildly disabled patients with little cognitive impairment and using the SF-36 measure described outcomes significantly worse than healthy individuals (Bugge, Hagen et al. 2001) and these findings are consistent with other studies using different outcome measures (Haacke, Althaus et al. 2006). Conversely, a more recent Australian study reported outcomes close to healthy patients (Anderson 2000; Anderson 2000). Normative data for the SF36 is available across versions and across countries (Jenkinson, Coulter et al. 1993), including Australia, and these data were utilised in the analyses of this study.

### Justification of choice of outcome measure

In the current study, no other measure combined quality of life with physical functioning, and given the well established validity and reliability of this measure, as well as the availability of normative values, it was chosen as an outcome measure for the SRO study.

Pre-testing of the authorized Australian version of the SF-36 among patients with stroke showed that a high proportion were unable to self-complete the questionnaire because of visual problems, confusion, and physical disability (McCallum 1995). Further, in a study of geriatric day unit stroke and musculoskeletal patients found that administration of SF36 by an interviewer is essential to obtain meaningful

results in older people with poor physical health (Fowler, Congdon et al. 2000). Consequently, although patients were asked to self-complete questionnaires that were posted to them prior to follow-up if it was possible for them to do so, these data were also then checked for completeness and ambiguity during face-to face interview by the assessor.

#### 4.4.9 Ten-metre walk test

Description, development, reliability and sensitivity of tool

Gait speed is a continuous measure with a natural zero, and published target gait speeds provide meaningful goals for treatment planning and clinical decision making (Salbach, Mayo et al. 2001). It has been found to be reliable (Flansbjerg, Holmback et al. 2005) and sensitive to change (English, Hillier et al. 2006).

It has been shown that the 6 and 12minute walk tests (6MWT, 12MWT) and self-paced gait speed over 10metres are all highly correlated with one another all also related to the severity of impairments. Stroke-specific impairments including weakness of the affected hip flexors and knee extensors are the major limitations to the distance walked in individuals with stroke (Eng, Chu et al. 2002). Gait velocity is less likely to show a ceiling effect than other measures given that it is only limited by the physical capacity of the individual and not the structure of the test (Salbach, Mayo et al. 2001).

Although various instructions have been published (Hsu, Tang et al. 2003), those used in the current study were: “I am going to measure your comfortable walking speed. When I say ‘go’, walk in a straight line at a pace which is safe and comfortable for you, until you reach the second pylon” (Salbach, Mayo et al. 2001).

Indications for using tool

The retraining of gait is a major focus in the rehabilitation of patients with stroke (Kim, Eng et al. 2004), with literature suggesting that the majority of patients will

walk again (Friedman 1990). Contrary to the gait of healthy individuals, which is fairly consistent in pattern across subjects, marked variation in gait patterns has been noted in patients with stroke (Kim, Eng et al. 2004). Gait performance in patients with stroke is characterized by slower gait velocity and residual spatial and temporal left-right asymmetry, compared with that of healthy adults (Hsu, Tang et al. 2003). Achieving normal gait patterns and speed are usually the ultimate goals of gait training (Lin, Yang et al. 2006), with gait speed predicting functional mobility and socialization (Jette, Keysor et al. 2005).

#### Clinically significant difference

Normative values have been published for both patients with stroke (Perry, Garrett et al. 1995) and non-stroke (Bohannon 1997) with minimal clinically important difference for acute stroke equal to 0.16m/s (Oberg, Karsznia et al. 1993; Tilson, Sullivan et al. 2010).

#### Justification of choice of outcome measure

As the retraining of walking is a major focus in the rehabilitation of persons with stroke (Kim, Eng et al. 2004), it was important to include a measure of gait performance to assess differences between facilities. The measurement of gait speed was chosen as it could be performed quickly and without equipment or space.

## CHAPTER 5

### Methods

#### 5.1 Introduction

The primary aim of the Stroke Rehabilitation Outcome (SRO) trial was to determine whether patients identified as having some potential to return to independent living as well as the ability to cope with intensive rehabilitation have better quality of life and functional outcome following rehabilitation at the stroke unit at Royal Perth Hospital–Shenton Park Campus (SPC SU) compared with a stroke unit located within a geriatric rehabilitation unit (GRU). The secondary aims were to determine whether there was a difference in the average amount of rehabilitation received by sub-acute stroke patients in the two different types of units (SPC SU versus GRU), and to make a preliminary assessment of the indirect costs associated with each type of facility based on length of hospital stay and amount of therapy input.

The SRO trial was initially designed as a randomized controlled trial (RCT). It was planned to recruit patients at the weekly acute stroke unit (ASU) team meetings at Royal Perth Hospital – Wellington Street Campus (RPH-WSC). The protocol for the proposed RCT is described in part 5.2 of this chapter. Despite comprehensive pilot work suggesting the feasibility of recruiting the required number of subjects in an appropriate time frame, recruitment was much more difficult than anticipated. Difficulties predominantly related to therapeutic equipoise made it impossible to proceed according to the intended randomized protocol and the study was revised into an observational trial, described in part 5.3 of this chapter. The aims of the observational study remained unchanged from those of the original RCT.

The primary Null Hypothesis was that there was no difference in functional outcome and quality of life of patients with stroke who met the inclusion criteria and received rehabilitation at SPC SU compared with a GRU.

## 5.2 Randomized controlled trial (RCT) protocol

### 5.2.1 Study design

The study was designed as a RCT whereby acute patients with stroke would be randomized into either rehabilitation group. Baseline data (Appendix 27) were to be collected from medical records, and inpatient length of stay (at both RPH-WSC and the subsequent rehabilitation facility) and amount of therapy, and functional status and quality of life would be measured at 6 and 12 months post-randomization (Figure 5.2.1a).

The study was approved by the ethics committees of Royal Perth Hospital (reference 2003/022), Bentley Health Service (reference 6/02), Mercy Hospital (reference MC/ad) and Swan Health Service (reference 7.23) and Curtin University (reference HR 192/2002). Copies of approval letters can be found in Appendix 28. It was not registered with the clinical trials registry, as this was not a requirement at the inception of the study.

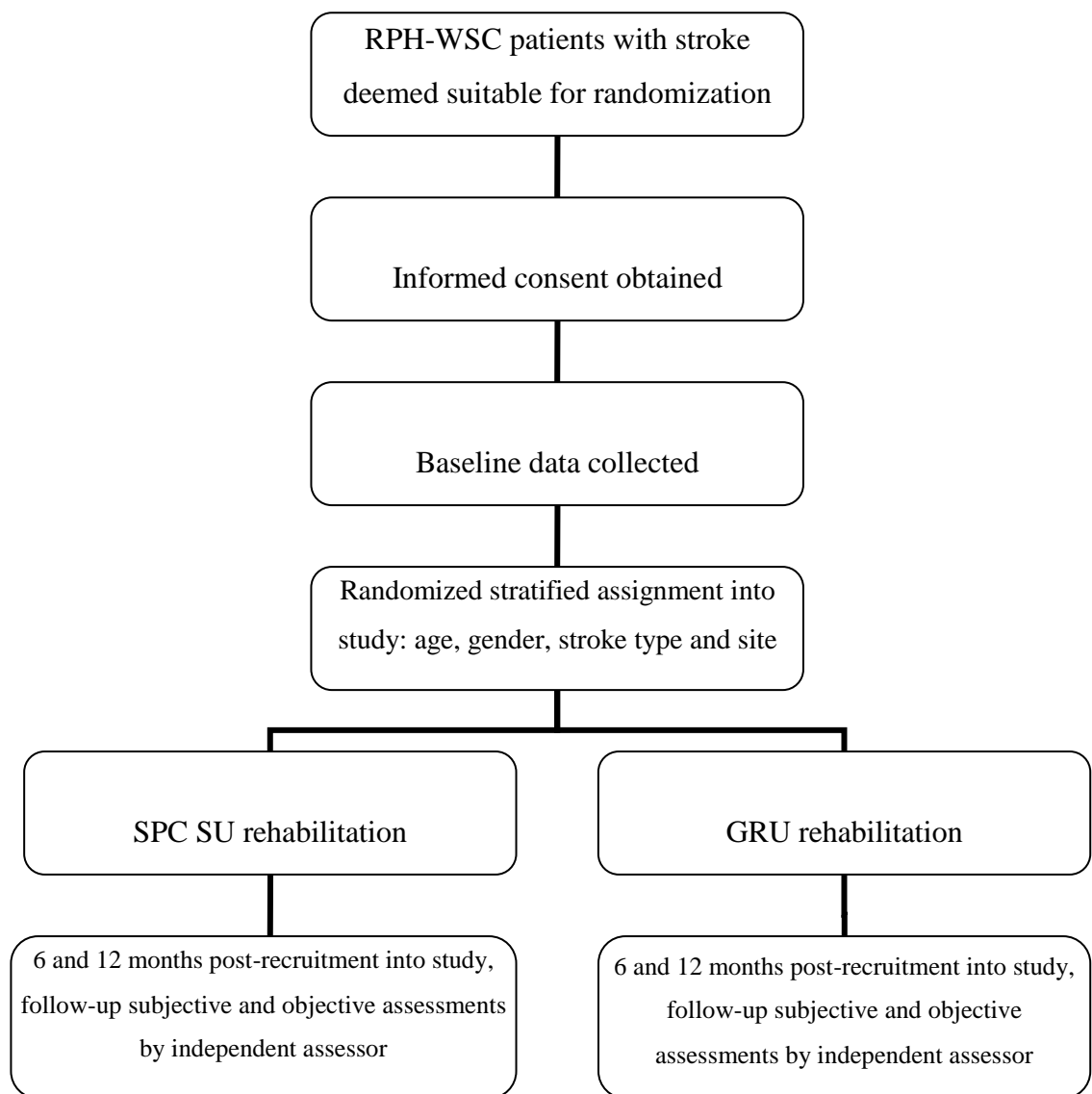


Figure 5.2.1a: Study design of SRO RCT

**SRO= Stroke Rehabilitation Outcome; RPH - WSC= Royal Perth Hospital – Wellington Street Campus; SPC SU= Royal Perth Hospital – Shenton Park Campus stroke unit; GRU=Geriatric rehabilitation unit**

## 5.2.2 Study population

### 5.2.2.1 Inclusions and exclusions

All patients presenting to RPH-WSC ASU with a diagnosis of recent stroke requiring hospitalisation and sub-acute rehabilitation were considered for inclusion into the study. Patients were to be invited into the study when the attending physician had no evidence to suggest advantages of SPC SU versus GRU rehabilitation. Patients younger than 60 years of age would be excluded as they would not normally be admitted to geriatric facilities. Older patients with no potential to return to some form of independent living or an inability to cope with intensive rehabilitation would also be excluded, as would those with pre-existing dementia. Those patients with any severe co-morbid condition that could cause death within one year; an inability to understand English well enough to complete assessments or sign consent; or those with geographic or social factors that were expected to impede study participation were also to be excluded.

### 5.2.2.2 Recruitment and patient consent

Patients were considered for inclusion in the study at weekly ward meetings involving all frontline staff at RPH-WSC ASU. Having been identified by the team, the senior medical registrar would explain the study to the patient and invite them to participate. Those potentially interested would be asked to read the Patient Information Sheet (Appendix 26), and given the opportunity to ask questions. Written consent would then be obtained from those wishing to volunteer (Appendix 26).

### 5.2.2.3 Power and sample size

Published data on the SF36 is widely available so this variable was used for a priori power calculations. Based on a within-group standard deviation of up to 18 points for 6 of the 8 SF36 domains, 50 patients per group would provide approximately



80% power to detect a 10 point difference in most of the SF36 domains if statistical significance was inferred at a 2-tailed  $p < 0.05$ . A difference of this magnitude is considered clinically meaningful by the SF36 developers. In addition, an allowance was made for a 16% dropout or loss to follow-up.

#### 5.2.2.4 Feasibility

Pilot data related to the number of patients with stroke presenting to RPH-WSC (Chapter 3, section 3.1.2) suggested that it would be feasible to recruit this number of stroke patients within 18 months.

### 5.2.3 Study procedure

#### 5.2.3.1 Baseline data collection

Baseline data (Appendix 27) would be collected from the medical notes of all patients after patient consent and prior to randomization, hence assessor blinding was not an issue. Where possible, these data would be derived from routine clinical assessment by RPH-WSC medical and AHP staff and collated for the purposes of this study. Any data not available from this source was collected separately for the study. The purpose of these data was to establish the underlying level of disability and compare groups for comparability. They would also be valuable as covariates in data analysis. Data included demographic information, social circumstance, past medical history, pre-morbid function, stroke classification and functional status at the time of consent into the study. Functional status was measured using measures previously outlined in Chapter 4. They included the Barthel Index (BI) score, Rankin score, Scandinavian Stroke score (SSS), Mini mental state examination (MMSE), 10m-walk time, Berg balance scale score (BBS) and Chedoke-McMaster tests. The number of days between admission and consent was also recorded.

#### 5.2.3.2 Randomization

Patient volunteers were to be randomized to continue their rehabilitation at either the SPC SU or the GRU geographically located closest to their home (Mercy, Swan or Bentley Hospitals). In order to be considered for randomization, patients would need to be reviewed and accepted for admission by medical staff from both relevant rehabilitation facilities. Those patients accepted for both facilities would then be randomized to determine their rehabilitation destination. To ensure groups were balanced for prognostic factors, randomization was to be stratified using the minimization method balancing groups for patient age ( $>$  or  $\leq$  75 years), gender (M or F), and stroke severity as defined by dependency at the time of randomization (mild stroke - BI 10-20/20 or moderate to severe stroke – BI  $<$ 10/20). This dynamic process would be administered by the clinical coordinator who did not have clinical contact with the participants and was not to be involved with recruitment. Recruitment was to take place prior to group assignment. Group assignment would not be simple to predict when stratifying across 3 factors.

#### 5.2.3.3 Treatment procedure and documentation

In this pragmatic trial, all treatments received would be those considered standard for the individual facility, administered as usual by registered rehabilitation/therapy health professionals.

#### 5.2.3.4 Follow-up procedure and outcome data collection

Six and twelve months following their transfer from RPH-WSC ASU, patients would attend follow-up outpatient appointments at neutral rooms where objective and subjective assessments would be undertaken by an independent assessor who would not be informed about which rehabilitation facility the patient had attended. The blind independent assessor was to be an experienced physiotherapist who had never worked at RPH-WSC previously to ensure previous knowledge of the patients would

not confound assessments. The duration of each assessment visit was planned to be approximately 1 hour.

#### 5.2.4 Implementation of protocol

Recruitment was commenced in late January 2003 by a research collaborator who planned to recruit the caregivers of the study patients for a concurrent study exploring the role of the caregiver in stroke recovery. This collaborator attended the medical and allied health team weekly ward meetings where ongoing rehabilitation and discharge plans of patients were discussed. Over 14 weeks, a total of 45 patients were age appropriate for the trial (Figure 5.2.4.1). Of these, 24 patients were excluded (13 discharged home; 2 transferred to country hospitals; 4 transferred to other medical specialties within RPH-WSC; 3 discharged directly to permanent care; and 2 with poor understanding of the English language) and 10 had no discussion of discharge planning at the team meeting. This left 11 potential patients suitable for randomization, however none of these were able to be recruited. The reasons for this included clinical staff deciding they should be directed to one facility in preference to the other (for example, one patient who made “better than expected early improvements” at RPH-WSC being directed to SPC SU where they considered rehabilitation would be more appropriate) and patient or family preference (for example, where the geographical location of a GRU enabled an elderly spouse to visit his wife more frequently).

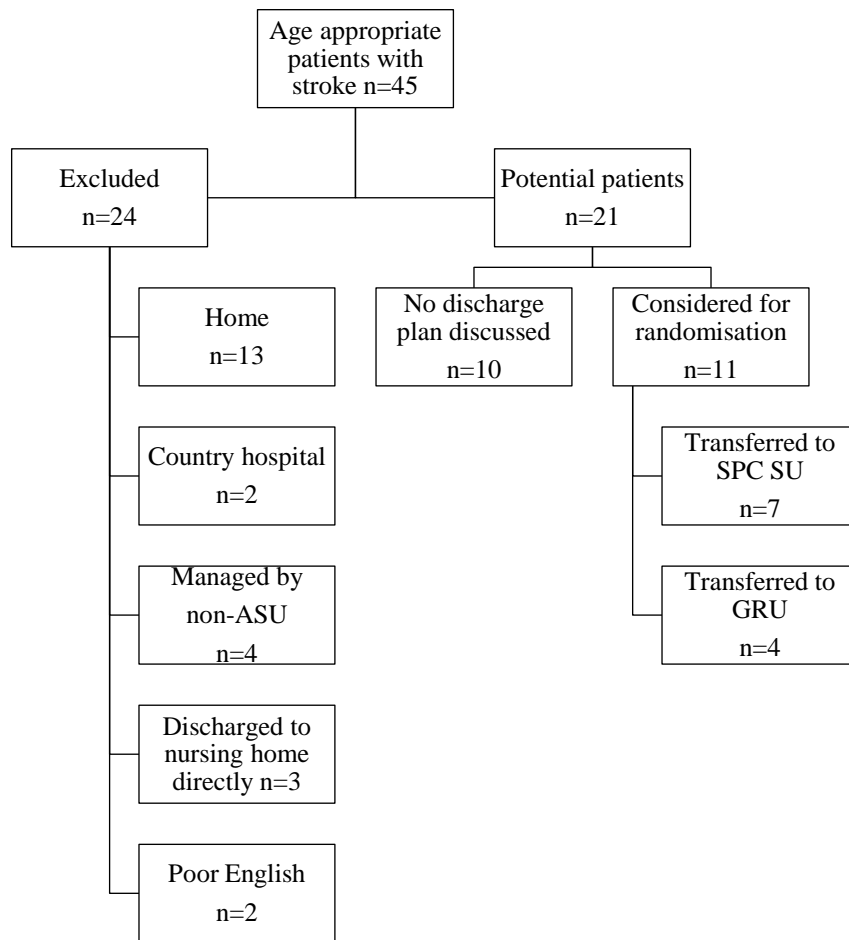


Figure 5.2.4.1: Initial RCT recruitment period

Recruitment was suspended in May 2003 in order that the primary investigator could meet and discuss the randomization process with key RPH-WSC medical and allied health staff. Following meetings with key staff, it was decided that it may be more feasible to amend the study design and recommence the study using an observational rather than a randomized design. Using an amended design, all patients with stroke who met the inclusion criteria would be invited to participate and those who volunteered would be followed up at 6 and 12 months post-stroke no matter which type of rehabilitation facility they had attended. However, as this approach was less rigorous than the original randomized design, it was decided that one more trial of RCT recruitment should be undertaken before commencing an observational study.

At about the same time the collaborator who had been attending the ward meetings moved and could no longer continue her involvement with the project. Therefore, during the second attempt at recruitment, the principal investigator attended meetings and promoted the RCT.

After the Christmas 2003 break (where staffing was transient and discontinuous), the second period of recruitment began in February 2004. Over 12 weeks, the principal investigator attended all weekly ASU ward team meetings. During this time 26 new patients were age appropriate for the trial (Figure 5.2.4.2). Of these, 12 patients were excluded (8 discharged home; 1 transferred to country hospitals; 1 transferred to other medical specialties within RPH-WSC; 2 discharged directly to permanent care) and 3 had no discussion of discharge planning. This left 11 potential patients suitable for randomization, however none were able to be recruited. Once again, no patients could be recruited based on clinical decision making or family preference for one facility over another.

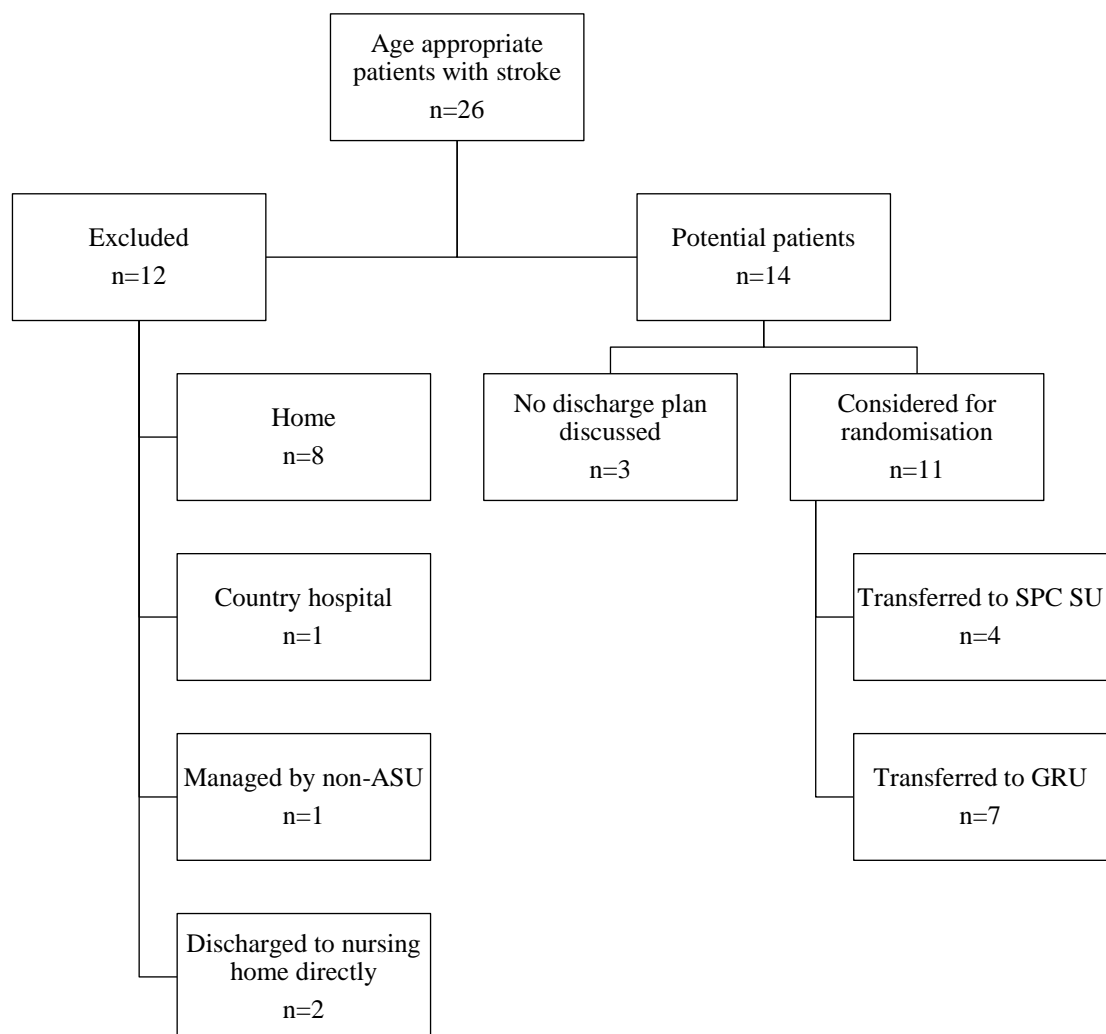


Figure5.2.4.2: Second RCT recruitment period

### 5.2.5 Discussion

After a total of 6 months of recruitment no patients had been recruited for the study. Attendance at the weekly team meetings and discussions with the rehabilitation staff revealed that there were strong preconceived ideas about the rehabilitation facilities that prompted staff to form opinions about the “best fit” rehabilitation facility for any prospective patient. This led to reluctance by these staff to sanction randomization of patients despite the lack of empirical evidence to inform decisions about which patients should go to which facility. These preconceptions may or may not have been held by incumbent staff at the SPC SU or GRUs (see Chapter 3, section 3.2.1), and may or may not have been accurate. It should be recognized however that staff attending the RPH-WSC ASU team meetings were very experienced in dealing with patients with stroke.

Reasons offered for why patients should be referred to one or other facility included that:

- therapy was more intensive at SPC SU compared with the GRUs.
- patients suitable for referral to SPC SU needed to have the capacity to cope with more intensive therapy.
- the patient’s capacity to cope with rehabilitation may be indirectly proportional to the number of co-morbidities present.
- patients needed to be motivated for best outcome at SPC SU.
- some GRUs did not have appropriate AHP staffing (in particular speech pathologists) to provide optimal treatment for some patients.

### 5.2.6 Conclusion

Despite support for the trial by the RPH-WSC ASU medical team, and full ethics approval from all hospitals involved, no patients were successfully recruited into the trial over two periods, lasting a total of 26 weeks. Ultimately, based on their clinical experience and perceptions about the different rehabilitation facilities, AHPs at the RPH-WSC ASU felt ethically obliged to recommend one or other rehabilitation

course for their patients despite the lack of objective evidence for these perceptions. It was similarly ethically difficult for the author to influence staff in any way, given their views. To a lesser extent, patients' preference to be transferred to facilities closer to home also had a negative effect on recruitment.

The inability to recruit subjects for randomization into the study required there to be significant changes to the methodology. Although less rigorous, it was decided to amend the study, changing from an experimental to an observational design. The aims of the observational study remained unchanged from those of the original RCT.

### 5.3 Observational trial protocol

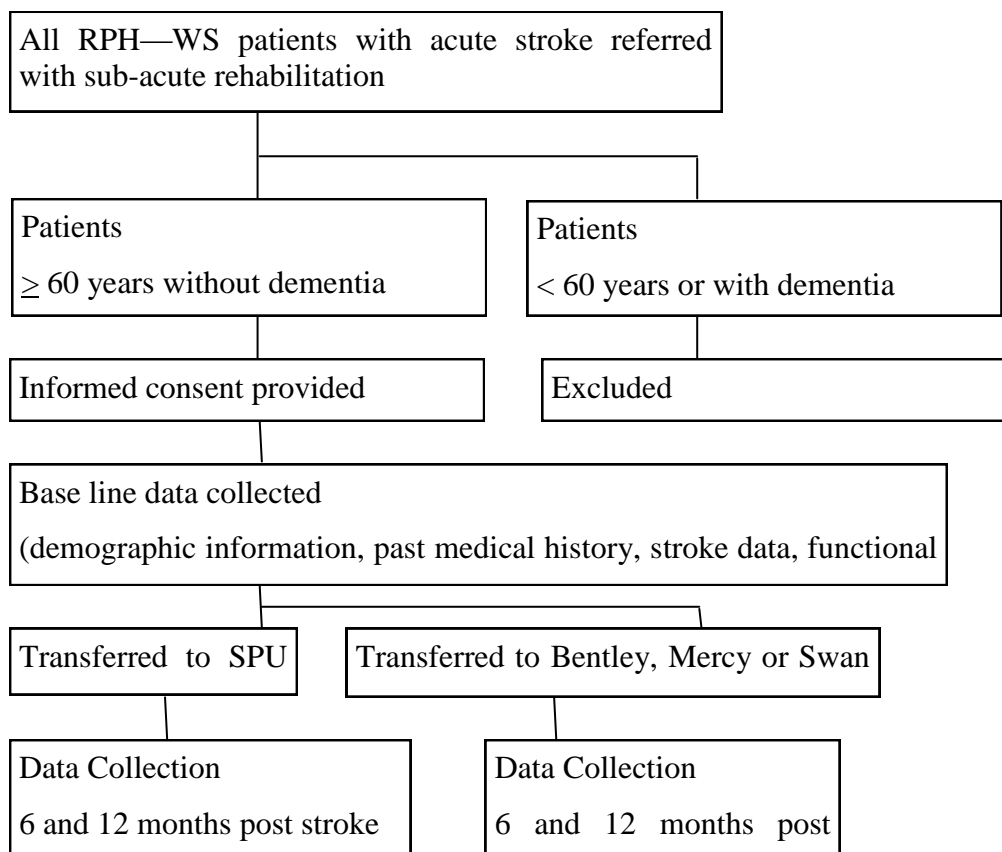
#### 5.3.1 Study design

The study was an inception cohort study whereby patients were selected based on their age, absence of dementia and their acceptance by incumbent medical staff for rehabilitation transfer at either SPC SU or a GRU (Figure 5.3.1a).

The amended study design was submitted to and approved by the ethics committees of Royal Perth Hospital (reference 2003/022), Bentley Health Service (reference 6/02), Mercy Hospital (reference MC/ad) and Swan Health Service (reference 7.23) and Curtin University (reference HR192/2002).



Figure 5.3.1a: Study design of SRO observational trial



**SRO= Stroke Rehabilitation Outcome; RPH - WSC= Royal Perth Hospital – Wellington Street Campus; SPC SU= Royal Perth Hospital – Shenton Park Campus stroke unit; GRU=Geriatric rehabilitation unit**

### 5.3.2 Study population

#### 5.3.2.1 Inclusions and exclusions

No adjustments were made to the inclusion and exclusion criteria (see 5.2.2.1) or sample size (see 5.2.2.3).

#### 5.3.2.2 Recruitment and patient consent

All patients from RPH-WSC with acute stroke requiring further rehabilitation were identified and screened according to the standard referral procedures for the ASU (Appendix 25). This system involved a written referral to the SPC SU or one of the GRUs. Written referrals were followed up by the medical staff from the unit specified and if the patient was deemed appropriate, transfer was arranged. For the purposes of the study, all referrals were copied by the medical units receiving them, and these referrals were collected and reviewed on a biweekly basis by a research assistant employed for the study to identify patients suitable for the SRO trial.

A research assistant obtained informed written consent from all participants prior to commencement of data collection (Appendix 26). All procedures were clearly explained to each participant, and it was made clear that they had the right to withdraw from the study at any time without prejudice to their ongoing medical care.

### 5.3.3 Study procedure

#### 5.3.3.1 Baseline data collection

The same baseline data (Appendix 27) were collected as proposed for the RCT design (see 5.2.3.1).

#### 5.3.3.2 Transfer procedure

Participants were transferred to continue their rehabilitation at either the SPC SU or the GRU geographically located closest to their home or the home of their primary caregiver (within Bentley, Mercy or Swan hospital). If bed availability delayed transfer to the rehabilitation unit, the number of days delayed was recorded as part of baseline data in order to assess differences between facilities at this timepoint. If transfer was delayed patients continued to receive usual care from staff in the ASU at RPH-WSC while awaiting transfer as per normal practice. If patients awaiting transfer recovered sufficiently at RPH-WSC ASU for direct discharge home, then this was recorded. If patients were discharged home directly from RPH-WSC they were excluded from the data set, as their outcome was no longer influenced by their sub-acute rehabilitation stay.

#### 5.3.3.3 Treatment procedure and documentation

All allied health professionals (AHPs) involved in the management of patients in the trial had the opportunity to attend information sessions where they were made aware of the study design and data collection. Ongoing education of new staff was attended to as the need arose at each facility.

In this pragmatic trial, all treatments provided were standard for the individual facility and administered as usual by incumbent AHPs. Participating patients were provided with an AHP treatment diary (see Chapter 3, section 3.2.2), where AHPs recorded the date, duration and location of all treatments received by that patient. In addition, behaviour mapping was conducted for 2 consecutive days once every 2 months at each facility for the duration of the trial (see Chapter 7).

#### 5.3.3.4 Follow-up procedure

The protocol for follow-up procedure remained as planned for the RCT design. Patients were instructed not to disclose the facility where they received rehabilitation

to the assessor. Self-completed questionnaires were mailed to patients prior to these appointments to allow completion ahead of time. Questionnaires were checked for missing data at the time of the appointment.

#### 5.3.4 Outcome measures

Health outcomes were selected in consultation with clinicians with recognized expertise in the management of stroke, taking into account validity, reliability and responsiveness in the stroke population. All chosen variables have been previously discussed in Chapter 4 and are widely used in published studies. The independent variable was the group assignment to either rehabilitation at the SPC SU or one of 3 GRUs. The dependant variables covered 6 domains:

##### 5.3.4.1 Quality of life

- MOS 36-Item Short Form Health Survey (SF-36)
- European Quality of life 5 dimension visual analogue scale (EQ5D VAS)
- Hospital Anxiety and Depression (HAD) scale

##### 5.3.4.2 Function

- Functional independence measure (FIM)
- Berg balance scale score (BBS)
- Ten metre walk test
- Chedoke McMaster shoulder pain inventory
- Chedoke McMaster postural control impairment inventory
- Action Research Arm (ARAT) test

##### 5.3.4.3 Treatment environment: behaviour mapping

Behaviour mapping was used to monitor and characterize the rehabilitation setting and aspects of treatment. Pilot data (see Chapter 3, section 3.2.3) indicated that the

mapping data were sensitive to variations in the rehabilitation environment within and between facilities.

#### 5.3.4.4 Cost: Length of stay and AHP diary information

- The length of inpatient stay within the rehabilitation facility
- The frequency and duration of therapy: Information was generated from the patient diaries. Pilot data (see Chapter 3, section 3.2.2) indicated that the diaries were sensitive to variations in the way rehabilitation was administered within and between facilities. These data were used to compare the treatment frequency and duration at each type of facility.

#### 5.3.4.5 Discharge outcome

- Discharge destination

### 5.4 Statistical methods

Data were analysed using Statistical Package for the Social Sciences (SPSS® version, IBM USA and other countries) and statistical significance was set at  $\alpha=0.05$ . Descriptive statistics were reported as counts (percentage) for categorical data and for continuous data mean (SD) for normally distributed data or median (IQR) where data were not normally distributed. Characteristics of patients at baseline were compared between facilities using Pearson Chi-Square for categorical variables and unpaired t-tests or Mann-Whitney tests as appropriate for continuous variables.

Multilevel linear models were used to compare rehabilitation outcomes between SPC SU and GRU. Additional factors included as covariates in the models were age, gender, and baseline Barthel Index score. Separate models were constructed for each of the dependent variables.

Generalized estimating equations were used to compare rehabilitation outcomes between SPC SU and GRU. Additional factors included as covariates in the models were age, gender, baseline Barthel Index score and visit as a repeated factor. Separate models were constructed for each of the 10 dependent variables but adjustments for multiple comparisons were not implemented to reduce the risk of Type II error (Perneger 1998; Feise 2002).

## CHAPTER 6

### RESULTS

#### 6.1 Introduction

This chapter reports the results of the stroke rehabilitation outcome (SRO) observational study that compared functional outcome of a group of stroke patients receiving rehabilitation at a neurological stroke unit located at Royal Perth Hospital – Shenton Park campus (SPC SU) with a group of patients receiving rehabilitation at a geriatric rehabilitation unit (GRU) (at either Bentley, Mercy or Swan hospital) with 6 and 12 month follow-up. Ninety-four patients with stroke were recruited from the Royal Perth Hospital – Wellington Street campus (RPH-WSC) acute stroke unit between June 2004 and November 2006.

#### 6.2 Patient flow

Since 1999/2000 when pilot data were first collected for the study (see Chapter 3, *section 3.1.2*), data from RPH-WSC the annual number of patients discharged with the diagnosis of stroke increased by almost 50 percent (Table 6.2a).

Table 6.2a: Annual number of patients discharged from RPH-WSC with the diagnosis of Stroke

| Year      | Number of patients |
|-----------|--------------------|
| 1999/2000 | 531                |
| 2000/2001 | 695                |
| 2001/2002 | 659                |
| 2002/2003 | 767                |
| 2003/2004 | 853                |
| 2004/2005 | 798                |
| 2005/2006 | 922                |
| 2006/2007 | 802                |

Although the SRO study recruited subjects for 30 months between July 2004 and December 2006, only annual hospital data was available to the author. Thus, during the 36 months between July 2004 and June 2007, 2522 patients with stroke presented to RPH-WSC. Of these, 550 patients were assessed and treated at the ASU, the remaining patients were treated in other areas of the hospital (Figure 6.2a).



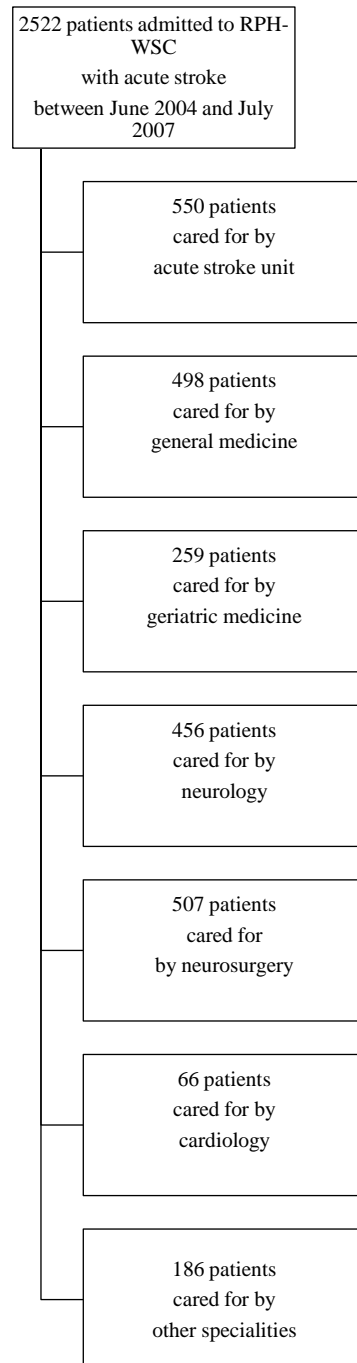


Figure 6.2a: Inpatient destination of all patients with Stroke following admission to RPH-WSC between July 2004 and June 2007

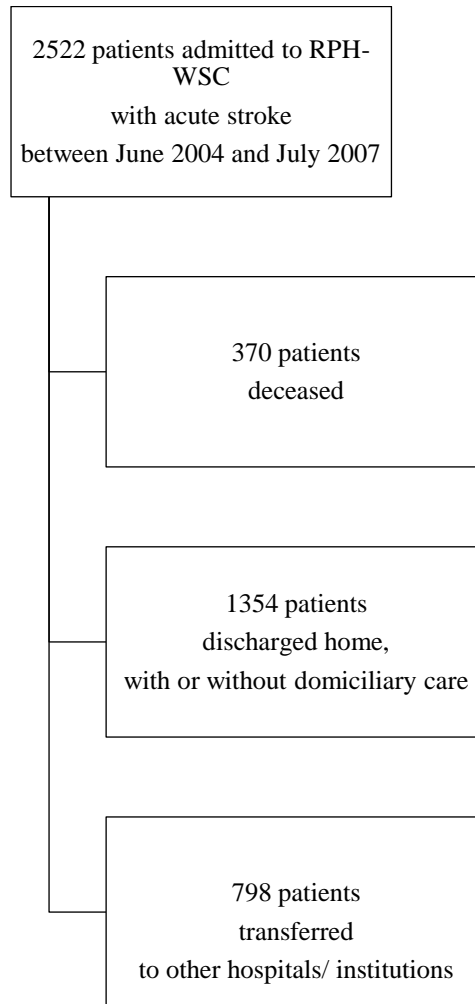


Figure 6.2b: Discharge Destination of all patients with Stroke following admission to RPH-WSC between July 2004 and June 2007

Of the total cohort of 2522 patients, 370 died as inpatients. A further 1354 were discharged directly home from the hospital, with or without domiciliary support and under the care of their general practitioner. The remaining 798 were transferred to other facilities (Figure 6.2b)

Of the 798 patients that were transferred to another hospital or institution between July 2004 and June 2007, 524 patients with stroke transferred to the facilities involved in this trial (Figure 6.2c: SPC SU n=250; GRUs n=274). The remaining 274 patients transferred to one of 14 other metropolitan hospitals (106 patients),

various nursing home/ hostels (93 patients), country hospitals (56 patients), interstate/ overseas hospitals (8 patients) or hospice care (11 patients).

Of the 524 patients that transferred to the facilities included in the SRO trial, there were 354 who were age appropriate (60 years of age or older) for recruitment into the study (Figure 6.2c: SPC SU n=84; GRUs n=270). Of these, 94 consented to participate (SPC SU n=22; GRUs n=72). This reflected an overall recruitment rate of 26.5% (SPC SU 26%; GRU 27%).

### 6.3 Baseline Data

Patients referred to SPC SU were younger, more likely to be male, and have speech abnormality, peripheral vascular disease and diabetes than those referred to GRUs. Otherwise there were no significant differences between groups in demographic (Table 6.3.1) admission characteristics (Table 6.3.2) or past medical history (Table 6.3.3) measured at baseline.

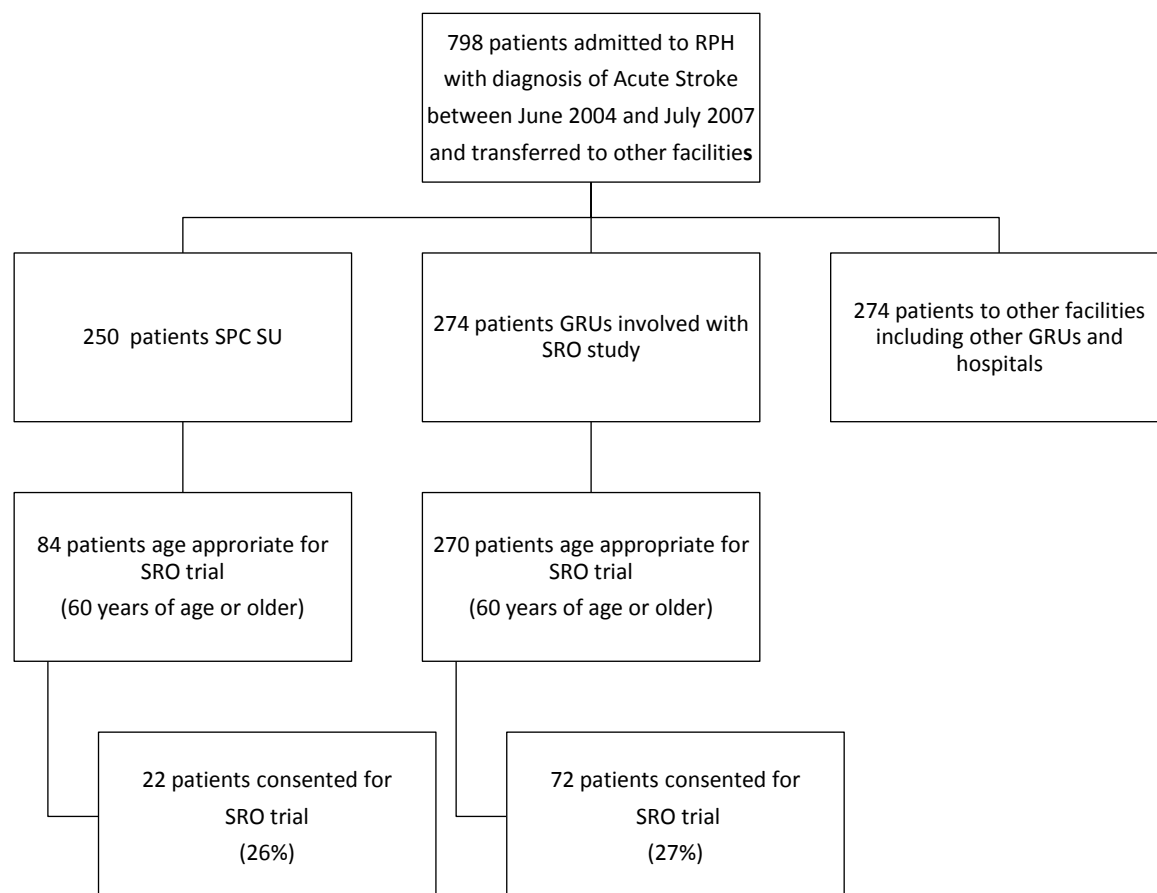


Figure 6.2c: Destination of patients with Stroke transferred to other facilities following admission to RPH-WSC between July 2004 and June 2007, and recruitment of age appropriate patients into the SRO trial.

Table 6.3.1: Demographic characteristics of patients (n=94)

| Variable                           | SPC SU<br>n=22 | GRU<br>n=72  | P value                      |
|------------------------------------|----------------|--------------|------------------------------|
| Gender                             |                |              | <b>0.009</b>                 |
| • Male                             | 19 (86.4)      | 40 (55.6)    |                              |
| • Female                           | 3 (13.6)       | 32 (44.4)    |                              |
| Age, mean (SD)                     | 63.95 (4.32)   | 77.19 (8.25) | <b>&lt;0.001<sup>^</sup></b> |
| Living Arrangements Pre-Stroke     |                |              | 0.073                        |
| • Alone                            | 5 (22.7)       | 29 (40.3)    |                              |
| • With Relative other than partner | 0              | 6 (8.3)      |                              |
| • With Partner                     | 17 (77.3)      | 37 (51.4)    |                              |
| Level of function Pre-Stroke       |                |              | 0.429                        |
| • Independent                      | 22 (100)       | 70 (97.2)    |                              |
| • Dependent                        | 0              | 2 (2.8)      |                              |
| Stroke Site                        |                |              | 0.599                        |
| • Right                            | 9 (40.9)       | 34 (47.2)    |                              |
| • Left                             | 13 (59.1)      | 36 (50)      |                              |
| • Brainstem                        | 0              | 2 (2.8)      |                              |
| Stroke Pathology                   |                |              | 0.685                        |
| • Ischaemic                        | 18 (81.8)      | 56 (77.8)    |                              |
| • Haemorrhagic                     | 4 (18.2)       | 16 (22.2)    |                              |
| Stroke Type                        |                |              | 0.689                        |
| • LAC                              | 5 (22.7)       | 22 (30.6)    |                              |
| • TAC                              | 8 (36.4)       | 18 (25)      |                              |
| • POC                              | 1 (4.5)        | 6 (8.3)      |                              |
| • PAC                              | 8 (36.4)       | 26 (36.1)    |                              |

Data presented as number (%) unless indicated; p value for Pearson Chi-Square; <sup>^</sup>p value for t-test; LAC= lacunar infarction; TAC= total anterior circulation infarction; PAC=partial anterior circulation infarction; POC=posterior circulation infarction

Table 6.3.2: Admission status of patients (n=94)

| Variable                            | SPC SU<br>n=22 | GRU<br>n=72   | P value      |
|-------------------------------------|----------------|---------------|--------------|
| BI total score, mean (SD)           | 38.86 (28.91)  | 30.70 (25.78) | 0.211^       |
| BBB mean (SD)                       | 18.05 (18.17)  | 16.01 (13.92) | 0.583^       |
| CMM shoulder inventory, mean (SD)   | 3.68 (1.43)    | 3.42 (1.34)   | 0.513^       |
| CMM postural inventory, mean (SD)   | 3.68 (1.43)    | 3.42 (1.34)   | 0.436^       |
| MMSE score, mean (SD)               | 23.43 (6.69)   | 19.95 (7.20)  | 0.104*^      |
| Rankin score, mean (SD)             | 3.91 (1.06)    | 4.18 (0.70)   | 0.165^       |
| SSS – prognostic, mean (SD)         | 15.82 (4.93)   | 16.79 (3.71)  | 0.325^       |
| SSS – long term, mean (SD)          | 23.59 (12.52)  | 26.20 (11.35) | 0.361^       |
| Abnormal language present           | 10 (45.5)      | 15 (20.8)     | <b>0.022</b> |
| Abnormal speech present             | 17 (77.3)      | 48 (66.7)     | 0.346        |
| Abnormal swallow present            | 5 (22.7)       | 22 (30.6)     | 0.478        |
| Visual field loss/ diplopia present | 3 (13.6)       | 15 (20.8)     | 0.453        |
| Vertigo present                     | 0              | 2 (2.8)       | 0.429        |
| Sensory deficit arm or leg present  | 6 (27.3)       | 21 (29.2)     | 0.864        |
| Weakness arm or leg present         | 20 (90.9)      | 63 (87.5)     | 0.663        |
| Ataxia present                      | 3 (13.6)       | 5 (6.9)       | 0.325        |
| Incontinence present                | 0              | 7 (9.7)       | 0.128        |
| Facial muscle weakness present      | 8 (36.4)       | 31 (43.1)     | 0.577        |

**Data presented as number (%) unless indicated; p value for Pearson Chi-Square; ^p value for t-test; BI= Barthel Index; BBB= Berg balance score; CMM= Chedoke McMaster; MMSE= Mini mental state examination; SSS=Scandinavian stroke score**

Table 6.3.3: Past medical history of patients (n=94)

| Variable   | SPC SU<br>n=22 | GRU<br>n=72 | P value          |
|--|----------------|-------------|------------------|
| Smoking History  |                |             | 0.098            |
| • Non-Smoker   | 9 (40.9)       | 44 (61.1)   |                  |
| • Current Smoker   | 4 (18.2)       | 4 (5.6)     |                  |
| • Past Smoker  | 9 (40.9)       | 24 (33.3)   |                  |
| Stroke   | 2 (9.1)        | 14 (19.4)   | 0.258            |
| Transient Ischaemic Attack   | 2 (9.1)        | 14 (19.4)   | 0.258            |
| Myocardial Infarction  | 3 (13.6)       | 7 (9.7)     | 0.602            |
| Hypertension   | 13 (59.1)      | 55 (76.4)   | 0.112            |
| Peripheral Vascular Disease  | 4 (18.2)       | 2 (2.8)     | <b>0.010</b>     |
| Diabetes   | 12 (54.5)      | 12 (16.7)   | <b>&lt;0.001</b> |
| Ischaemic Heart Disease  | 3 (13.6)       | 15 (20.8)   | 0.453            |
| Atrial Fibrillation  | 2 (9.1)        | 14 (19.4)   | 0.258            |
| Hypercholesterolaemia  | 8 (36.4)       | 24 (33.3)   | 0.793            |
| Coronary Artery Bypass Grafting  | 2 (9.1)        | 7 (9.7)     | 0.930            |
| Depression   | 2 (9.1)        | 1 (1.4)     | 0.072            |
| Alcohol Abuse  | 0              | 4 (5.6)     | 0.259            |
| Psychiatric history  | 0              | 0           |                  |
| <b>Data presented as number (%) unless indicated; p value for Pearson Chi-Square</b> |                |             |                  |

#### 6.4 Outcome data

Rehabilitation data (Tables 6.4.1 to 6.4.3) demonstrated no significant differences in either the number of days between stroke and transfer ( $p=0.201$ ) or the number of days between referral and transfer ( $p=0.403$ ). Length of stay was longer at SPC SU ( $p=0.036$ ; Table 6.4.1) and absolute duration of time spent by AHP on therapy/treatment, administration and indirect support, was significantly greater at SPC SU compared with GRUs. Similarly overall occasions of service split by profession (Table 6.4.1) also reflected significant differences in occupational therapy, speech therapy and social work with SPC SU staff delivering more occasions of service. There was no difference between facilities in the occasions of service provided by physiotherapists. There was also no significant difference in the number of different health professions providing treatment between facilities ( $p=0.191$ ; Table 6.4.1). Professions such as podiatrists, dietitians and clinical psychologists were among those providing treatment, however their numbers were not reported as they represent only a small component of overall allied health attendance. When both total AHP and individual profession occasions of service were expressed as occasions of service per week, consequently adjusting for LOS, the overall and physiotherapy only occasions of service did not differ between facilities but the number of services provided at SPC SU by occupational and speech therapy were still significantly greater than the GRUs. There was also no significant difference in discharge destination between facilities ( $p=0.312$ ; Table 6.4.2).



Table 6.4.1: Unadjusted rehabilitation data

|  | SPC SU,<br>Median (IQR) | GRU,<br>Median (IQR) | P value                      |
|--|-------------------------|----------------------|------------------------------|
| Time between stroke and transfer to rehabilitation, days                   | 23 (42)                 | 20 (18)              | 0.201                        |
| Time between referral and transfer to rehabilitation, days                 | 8 (17)                  | 8 (17)               | 0.403                        |
| Length of rehabilitation stay, days  | 53 (124)                | 39 (39)              | <b>0.036</b>                 |
| AHP Time*  |                         |                      |                              |
| Total AHP time, hours  |                         |                      |                              |
| • Therapy  | 65.7 (135.4)            | 18.1 (21.8)          | <b>&lt;0.001</b>             |
| • Administration   | 8.0 (7.2)               | 4.8 (4.8)            | <b>0.034</b>                 |
| • Indirect support   | 4.2 (6.2)               | 2.1 (2.8)            | <b>&lt;0.001</b>             |
| Total AHP time, minutes per weekday  |                         |                      |                              |
| • Therapy  | 99.2 (53.3)             | 39.6 (32.9)          | <b>&lt;0.001</b>             |
| • Administration   | 12.7 (9.7)              | 11.8 (9.4)           | 0.957                        |
| • Indirect support   | 6.8 (5.2)               | 3.9 (3.6)            | <b>0.022</b>                 |
| Total number of professions delivering AHP, number per patient per weekday | 3 (2-3)                 | 3 (2-5)              | 0.191                        |
| AHP Occasions of Service*  |                         |                      |                              |
| Total number AHP occasions of service                                      | 75.5 (220)              | 56.0 (59.0)          | <b>0.020</b>                 |
| • Physiotherapy  | 31.0 (72.0)             | 25.0 (26.0)          | 0.084                        |
| • Occupational Therapy   | 33.0 (118.0)            | 19.0 (27.0)          | <b>0.012</b>                 |
| • Speech Therapy, n(%)   | 13 (72.0)               | 25 (42.4)            | <b>0.033<sup>^</sup></b>     |
| • Social Work, n (%)   | 1 (5.9)                 | 29 (49.2)            | <b>&lt;0.001<sup>^</sup></b> |
| Total number AHP occasions of service per week                             | 11.9 (3.9)              | 9.0 (5.3)            | 0.055                        |
| • Physiotherapy  | 5.1 (1.4)               | 4.7 (2.6)            | 0.592                        |
| • Occupational Therapy   | 5.0 (1.5)               | 3.9 (3.3)            | <b>0.042</b>                 |
| • Speech Therapy <sup>†</sup>  | 2.3 (2.0)               | 0.6 (0.8)            | <b>&lt;0.001</b>             |

Data presented as median (IQR) unless stated otherwise; p value for Mann-Whitney U Test except for <sup>^</sup>p value for Pearson Chi-Square; \*data only available for 77 (82%) of patients; <sup>†</sup>data relates to only those patients receiving speech therapy, SPC SU n=13 and GRU n=25; AHP=Allied health professional

Table 6.4.2: Discharge destination of patients (n=94)

| Discharge destination, number (%) |           | 0.312     |
|-----------------------------------|-----------|-----------|
| • Usual home                      | 19 (86.4) | 49 (68.1) |
| • Hostel                          | 0         | 6 (8.3)   |
| • Another acute hospital          | 0         | 1 (1.4)   |
| • Another non-acute hospital      | 1 (4.5)   | 1 (1.4)   |
| • Nursing home                    | 1 (4.5)   | 13 (18.1) |
| • Deceased                        | 1 (4.5)   | 2 (2.8)   |

**Data presented as number (%); p value for Pearson Chi-Square**

As the study was not randomized, age and gender, which differed between groups at baseline, and Barthel Index score, known to be associated with length of stay in stroke patients, were included as covariates in the models presented in the tables following.

Differences between facilities in LOS remained significant ( $p < 0.001$ ; Table 6.4.3), as did overall AHP time in terms of therapy, administration and indirect support (Table 6.4.4). Moreover, even after AHP time was expressed as minutes per weekday the difference between therapy time remained significant with overall differences between the facilities of the order of 40 minutes per day. It is of interest that age was also a significant predictor of therapy time indicating that older patients received less therapy minutes regardless of which facility they were admitted to.

Table 6.4.3: Adjusted Length of rehabilitation stay data

|                                     | Estimated marginal mean<br>(SE) | Adjusted $\beta$ value<br>(95% CI) | p-value          |
|-------------------------------------|---------------------------------|------------------------------------|------------------|
| Length of rehabilitation stay, days |                                 |                                    |                  |
| SPC SU                              | 99.6 (10.2)                     |                                    |                  |
| GRU                                 | 50.6 (5.0)                      | -49.1 (-72.8 to -25.3)             | <b>&lt;0.001</b> |
| Age (yrs)                           |                                 | 0.3 (-0.8 to 1.4)                  | 0.631            |
| Female sex                          |                                 | 4.8 (-12.8 to 22.5)                | 0.593            |
| Barthel Index                       |                                 | -1.0 (-1.3 to -0.7)                | <b>&lt;0.001</b> |

**Data are presented as estimated marginal means from generalized estimating equations (SE); SPC SU= Royal Perth Hospital – Shenton Park Campus Stroke Unit; GRU=Geriatric rehabilitation unit**

After adjustment for covariates, total AHP occasions of service were more than double at SPC SU than GRUs (Table 6.4.4), however when expressed as a number per week the patients received the same average number of occasions of service regardless of facility. Age was not associated with the number of occasions of service.

When the absolute number of occasions of service were considered by profession the patients admitted to SPC SU were seen more often than those at the GRUs by each individual profession ( $p<0.003$ ; Table 6.4.5) even after adjustment for covariates. However, when expressed as the number of visits per week, physiotherapists and occupational therapists provided similar numbers of services per week at both types of facility ( $p>0.59$ ).

Prior to adjustment for the covariates age, gender, Barthel Index and the repeated factor “visit” (6 month and 12 month follow up) patients from SPC SU had significantly better outcomes for Berg balance score and Chedoke McMaster posture inventory ( $p<0.04$ ; Table 6.4.6). In addition, there were differences favoring the SPC SU group in the two general functional variables SF36PCS and FIM total that approached significance ( $p=0.064$  and  $p=0.102$  respectively). Differences between groups in the SF36 MCS score in favor of the GRU group also approached significance ( $p=0.088$ ) however there were no notable differences in either of the other two outcomes indicative of mental health (EQ5D or HAD). In adjusted models age and baseline Barthel Index were significantly associated with Berg balance, Chedoke McMaster posture inventory, SF36 PCS and FIM total. After adjustment for these and the other covariates there were no differences (significant or approaching significance) in outcome (Table 6.4.7).

Unadjusted and adjusted outcome scores at 6 and 12 months for the SPC SU and GRUs are shown in Tables 6.4.8 and 6.4.9 respectively. In general, changes in the 6 months between follow-ups were small, however it is interesting to note that “visit”

was significantly associated with SF36 PCS score and EQ5D in the adjusted models with improvements occurring with time in both of these outcomes.

Table 6.4.4: Adjusted AHP time\*

|  | Estimated marginal mean<br>(SE) | Adjusted $\beta$ value<br>(95% CI) | p-value          |
|--|---------------------------------|------------------------------------|------------------|
| Total AHP Therapy time, minutes                    |                                 |                                    |                  |
| SPC SU   | 5705.5 (716.9)                  |                                    |                  |
| GRU  | 1457.0 (354.2)                  | -4248.5 (-5926.6 to -2570.4)       | <b>&lt;0.001</b> |
| Age (yrs)  |                                 | -41.4 (-119.5 to 36.8)             | 0.300            |
| Female sex   |                                 | -250.4 (-1492.3 to 991.4)          | 0.693            |
| BI   |                                 | -45.17 (-66.3 to -24.1)            | <b>&lt;0.001</b> |
| Total AHP Therapy time, minutes per weekday        |                                 |                                    |                  |
| SPC SU   | 86.3 (7.4)                      |                                    |                  |
| GRU  | 45.9 (3.6)                      | -40.4 (-57.6 to -23.2)             | <b>&lt;0.001</b> |
| Age (yrs)  |                                 | -1.0 (-1.8 to -0.2)                | <b>0.010</b>     |
| Female sex   |                                 | -3.2 (-15.9 to 9.6)                | 0.625            |
| BI   |                                 | 0.03 (-0.2 to 0.2)                 | 0.744            |
| Total AHP Administration time, minutes             |                                 |                                    |                  |
| SPC SU   | 563.2 (76.6)                    |                                    |                  |
| GRU  | 372.2 (37.9)                    | -191.0 (-370.4 to -11.6)           | <b>0.037</b>     |
| Age (yrs)  |                                 | -1.7 (-10.1 to 6.6)                | 0.686            |
| Female sex   |                                 | -62.6 (-195.4 to 70.1)             | 0.355            |
| BI   |                                 | -3.8 (-6.1 to -1.5)                | <b>0.001</b>     |
| Total AHP Administration time, minutes per weekday |                                 |                                    |                  |
| SPC SU   | 9.6 (1.9)                       |                                    |                  |
| GRU  | 13.9 (0.9)                      | 4.3 (-0.2 to 8.8)                  | 0.060            |
| Age (yrs)  |                                 | -0.2 (-0.4 to -0.01)               | <b>0.033</b>     |
| Female sex   |                                 | -1.5 (-4.8 to 1.8)                 | 0.384            |
| BI   |                                 | 0.1 (0.02 to 0.1)                  | <b>0.008</b>     |
| Total AHP Support time, minutes                    |                                 |                                    |                  |
| SPC SU   | 352.8 (51.5)                    |                                    |                  |
| GRU  | 158.9 (25.4)                    | -193 (-314.4 to -73.3)             | <b>0.002</b>     |
| Age (yrs)  |                                 | -0.4 (-6.1 to 5.2)                 | 0.873            |
| Female sex   |                                 | 38.0 (-51.2 to 127.2)              | 0.404            |
| BI   |                                 | -2.4 (-3.9 to -0.9)                | <b>0.002</b>     |

|   |              |                         |        |
|---|--------------|-------------------------|--------|
| Total AHP Support time, minutes per weekday     |              |                         |        |
| SPC SU  | 5.8 (1.2)    |                         |        |
| GRU   | 5.4 (0.6)    | -0.4 (-3.1 to 2.4)      | 0.798  |
| Age (yrs)                                       |              | -0.1 (-0.2 to 0.04)     | 0.197  |
| Female sex                                      |              | 1.1 (-0.9 to 3.1)       | 0.278  |
| BI  |              | 0.03 (0 to 0.1)         | 0.068  |
| Total AHP occasions of service, number          |              |                         |        |
| SPC SU  | 148.2 (17.0) |                         |        |
| GRU   | 62.7 (8.4)   | -85.4 (-125.4 to -45.5) | <0.001 |
| Age (yrs)                                       |              | -0.1 (-2.0 to 1.7)      | 0.882  |
| Female sex                                      |              | -12.8 (-42.4 to 16.7)   | 0.396  |
| BI  |              | -1.2 (-1.7 to -0.7)     | <0.001 |
| Total AHP occasions of service, number per week |              |                         |        |
| SPC SU  | 11.0 (1.2)   |                         |        |
| GRU   | 10.7 (0.6)   | -0.3 (-3.1 to 2.5)      | 0.824  |
| Age (yrs)                                       |              | -0.1 (-0.2 to 0.01)     | 0.084  |
| Female sex                                      |              | -1.7 (-3.7 to 0.4)      | 0.113  |
| BI  |              | 0.02(-0.01 to 0.06)     | 0.201  |

**Data are presented as estimated marginal means from generalized estimating equations (SE);  
 \*data only available for 77 (82%) of patients; SPC SU= Royal Perth Hospital – Shenton Park  
 Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional;  
 BI=Barthel Index**

Table 6.4.5: Adjusted AHP input by profession\*

|   | Estimated marginal<br>mean (SE) | Adjusted $\beta$ value<br>(95% CI) | p-value          |
|---|---------------------------------|------------------------------------|------------------|
| Total number physiotherapy occasions of service                 |                                 |                                    |                  |
| SPC SU  | 57.5 (7.7)                      |                                    |                  |
| GRU   | 30.4 (3.8)                      | -27.1 (-45.1 to -9.0)              | <b>0.003</b>     |
| Age (yrs)   |                                 | 0.1 (-0.7 to 1.0)                  | 0.772            |
| Female sex  |                                 | -1.5 (-14.8 to 11.9)               | 0.830            |
| BI  |                                 | -0.5 (-0.8 to -0.3)                | <b>&lt;0.001</b> |
| Total number physiotherapy occasions of service per week        |                                 |                                    |                  |
| SPC SU  | 4.7 (0.6)                       |                                    |                  |
| GRU   | 5.0 (0.3)                       | 0.3 (-1.1 to 1.7)                  | 0.675            |
| Age (yrs)   |                                 | -0.02 (-0.1 to 0.04)               | 0.523            |
| Female sex  |                                 | -0.6 (-1.6 to 0.4)                 | 0.277            |
| BI  |                                 | 0.004 (-0.01 to 0.02)              | 0.673            |
| Total number occupational therapy occasions of service          |                                 |                                    |                  |
| SPC SU  | 66.8 (8.4)                      |                                    |                  |
| GRU   | 26.2 (4.2)                      | -40.6 (-60.4 to -20.8)             | <b>&lt;0.001</b> |
| Age (yrs)   |                                 | -0.1 (-1.1 to 0.8)                 | 0.785            |
| Female sex  |                                 | -7.6 (-22.4 to 7.2)                | 0.314            |
| BI  |                                 | -0.6 (-0.8 to -0.3)                | <b>&lt;0.001</b> |
| Total number occupational therapy occasions of service per week |                                 |                                    |                  |
| SPC SU  | 4.8 (0.6)                       |                                    |                  |
| GRU   | 4.4 (0.3)                       | -0.4 (-1.8 to 1.0)                 | 0.589            |
| Age (yrs)   |                                 | -0.04 (-0.1 to 0.02)               | 0.194            |
| Female sex  |                                 | -1.0 (-2.1 to 0.1)                 | 0.066            |
| BI  |                                 | 0.01 (-0.01 to 0.03)               | 0.288            |
| Total number speech therapy occasions of service^               |                                 |                                    |                  |
| SPC SU  | 31.6 (4.7)                      |                                    |                  |
| GRU   | 4.1 (3.1)                       | -27.5 (-39.6 to -15.3)             | <b>&lt;0.001</b> |
| Age (yrs)   |                                 | -0.1 (-0.8 to 0.5)                 | 0.664            |
| Female sex  |                                 | -3.9 (-13.7 to 5.8)                | 0.431            |
| BI  |                                 | -0.2 (-0.4 to -0.1)                | <b>0.005</b>     |



|  |            |                        |                  |
|--|------------|------------------------|------------------|
| Total number speech therapy occasions of service per week <sup>^</sup> |            |                        |                  |
| SPC SU   | 2.7 (0.3)  |                        |                  |
| GRU  | 0.8 (0.2)  | -1.8 (-2.7 to -1.0)    | <b>&lt;0.001</b> |
| Age (yrs)  |            | 0.01 (-0.04 to 0.06)   | 0.674            |
| Female sex   |            | 0.3 (-0.4 to 1.0)      | 0.434            |
| BI   |            | 0.01 (-0.001 to 0.02)  | 0.071            |
| Total number social work occasions of service <sup>†</sup>             |            |                        |                  |
| SPC SU   | 34.3 (5.4) |                        |                  |
| GRU  | 8.0 (0.9)  | -26.2 (-36.9 to -15.6) | <b>&lt;0.001</b> |
| Age (yrs)  |            | -0.2 (-0.4 to 0.1)     | 0.242            |
| Female sex   |            | -2.7 (-7.2 to 1.7)     | 0.230            |
| BI   |            | -0.1 (-0.2 to 0.1)     | 0.051            |

**Data are presented as estimated marginal means from generalized estimating equations (SE);**  
**\*data only available for 77 (82%) of patients; ^data relates to only those patients receiving**  
**speech therapy, SPC SU n=13 and GRU n=25; † data relates to only those patients receiving**  
**social work, SPC SU n=1 and GRU n=29; SPC SU= Royal Perth Hospital – Shenton Park**  
**Campus Stroke Unit; GRU=Geriatric rehabilitation unit; AHP=Allied health professional;**  
**BI=Barthel Index score**

Table 6.4.6: Unadjusted differences between groups in the outcome variables mean scores (SE) overall at both time points

|                                 | Total<br>population,<br>mean (SD) | SPC SU<br>n=22 | GRU<br>n=72 | P value |
|---------------------------------|-----------------------------------|----------------|-------------|---------|
| Primary variables:              |                                   |                |             |         |
| • SF36 MCS score                | 52.3 (11.5)                       | 48.9 (2.2)     | 53.3 (1.3)  | 0.088   |
| • SF36 PCS score                | 40.3 (10.3)                       | 43.2 (2.0)     | 39.0 (1.1)  | 0.064   |
| • FIM total score               | 99.9 (24.7)                       | 107.2 (5.4)    | 97.1 (3.0)  | 0.104   |
| Secondary variables:            |                                   |                |             |         |
| • ARAT total score              | 101.3 (20.2)                      | 100.5 (4.3)    | 100.4 (2.5) | 0.993   |
| • BBS                           | 34.0 (19.0)                       | 41.9 (4.2)     | 31.9 (2.3)  | 0.039   |
| • CMM shoulder inventory        | 4.6 (2.0)                         | 4.4 (0.4)      | 4.7 (0.2)   | 0.576   |
| • CMM posture inventory         | 4.4 (1.4)                         | 4.9 (0.3)      | 4.2 (0.2)   | 0.032   |
| • EQ5D VAS (centimetres)        | 6.4 (2.1)                         | 6.8 (0.4)      | 6.3 (0.2)   | 0.293   |
| • HAD score                     | 8.9 (7.0)                         | 8.8 (1.3)      | 9.0 (0.8)   | 0.880   |
| • Ten metre walk time (seconds) | 39.9 (122.1)                      | 33.7 (22.8)    | 41.8 (12.7) | 0.757   |

**Data presented as median (SE); ^p value for t-test; SF36=; MCS=Mental component summary score; PCS=Physical component summary score; FIM=Functional independence measure; ARAT=Action Research Arm Test; BBS= Berg balance score; CMM= Chedoke McMaster; EQ5D VAS=European Quality of Life-5 Dimension Visual Analogue Scale; HAD=Hospital anxiety and depression scale**

Table 6.4.7: Adjusted outcome variables at 6 and 12 months

|                   | Estimated marginal<br>mean (SE) | Adjusted $\beta$ value<br>(95% CI) | p-value          |
|-------------------|---------------------------------|------------------------------------|------------------|
| FIM Total (score) |                                 |                                    |                  |
| SPC SU            | 93.58 (5.6)                     |                                    |                  |
| GRU               | 99.99 (2.8)                     | 6.41 (-6.48 to 19.30)              | 0.330            |
| Age (yrs)         |                                 | -0.65 (-1.25 to -0.04)             | <b>0.036</b>     |
| Female sex        |                                 | 6.66 (-3.36 to 16.68)              | 0.193            |
| BI                |                                 | 0.51 (0.34 to 0.68)                | <b>&lt;0.001</b> |
| Visit             |                                 | -0.30 (-1.58 to 0.98)              | 0.648            |
| SF36 MCS (score)  |                                 |                                    |                  |
| SPC SU            | 49.92 (2.7)                     |                                    |                  |
| GRU               | 53.64 (1.4)                     | 3.71 (-2.70 to 10.12)              | 0.256            |
| Age (yrs)         |                                 | 0.03 (-0.28 to 0.33)               | 0.851            |
| Female sex        |                                 | -2.26 (-7.41 to 2.88)              | 0.389            |
| BI                |                                 | 0.02 (-0.07 to 0.11)               | 0.710            |
| Visit             |                                 | -0.70 (-4.12 to 2.72)              | 0.687            |
| SF36 PCS (score)  |                                 |                                    |                  |
| SPC SU            | 38.22 (2.2)                     |                                    |                  |
| GRU               | 40.12 (1.2)                     | 1.91 (-3.32 to 7.13)               | 0.475            |
| Age (yrs)         |                                 | -0.30 (-0.55 to -0.05)             | <b>0.018</b>     |
| Female sex        |                                 | 3.71 (-0.50 to 7.90)               | 0.083            |
| BI                |                                 | 0.08 (0.01 to 0.15)                | <b>0.033</b>     |
| Visit             |                                 | -6.05 (-8.70 to -3.40)             | <b>&lt;0.001</b> |
| ARAT (score)      |                                 |                                    |                  |
| SPC SU            | 96.14 (5.3)                     |                                    |                  |
| GRU               | 102.23 (2.7)                    | 6.09 (-6.14 to 18.33)              | 0.329            |
| Age (yrs)         |                                 | -0.11 (-0.65 to 0.42)              | 0.675            |
| Female sex        |                                 | -1.78 (-11.61 to 8.06)             | 0.723            |
| BI                |                                 | 0.34 (0.15 to 0.52)                | <b>&lt;0.001</b> |
| Visit             |                                 | -1.02 (-6.92 to 4.87)              | 0.733            |

|                                |             |                        |                  |
|--------------------------------|-------------|------------------------|------------------|
| BBS (score)                    |             |                        |                  |
| SPC SU                         | 28.5 (4.1)  |                        |                  |
| GRU                            | 35.0 (2.0)  | 6.53 (-3.0 to 16.0)    | 0.177            |
| Age (yrs)                      |             | -0.80 (-1.2 to -0.4)   | <b>&lt;0.001</b> |
| Female sex                     |             | 6.0 (-1.3 to 13.2)     | 0.108            |
| BI                             |             | 0.35 (0.2 to 0.5)      | <b>&lt;0.001</b> |
| Visit                          |             | -0.13 (-1.4 to 1.2)    | 0.844            |
| CMM shoulder inventory (score) |             |                        |                  |
| SPC SU                         | 3.95 (0.5)  |                        |                  |
| GRU                            | 4.89 (0.2)  | 0.94 (-0.16 to 2.04)   | 0.094            |
| Age (yrs)                      |             | -0.02 (-0.07 to 0.03)  | 0.406            |
| Female sex                     |             | -0.23 (-1.09 to 0.63)  | 0.602            |
| BI                             |             | 0.03 (0.02 to 0.05)    | <b>&lt;0.001</b> |
| Visit                          |             | -0.29 (-0.68 to 0.09)  | 0.138            |
| CMM posture inventory (score)  |             |                        |                  |
| SPC SU                         | 3.99 (0.3)  |                        |                  |
| GRU                            | 4.28 (0.2)  | 0.30 (-0.48 to 1.07)   | 0.454            |
| Age (yrs)                      |             | -0.04 (-0.07 to 0)     | <b>0.043</b>     |
| Female sex                     |             | 0.84 (0.23 to 1.45)    | <b>0.007</b>     |
| BI                             |             | 0.02 (0.02 to 0.04)    | <b>&lt;0.001</b> |
| Visit                          |             | -0.02 (-0.14 to 0.10)  | 0.780            |
| EQ5D VAS (centimetres)         |             |                        |                  |
| SPC SU                         | 6.95 (0.5)  |                        |                  |
| GRU                            | 6.31 (0.2)  | -0.64 (-1.80 to 0.51)  | 0.276            |
| Age (yrs)                      |             | 0.01(-0.04 to 0.07)    | 0.641            |
| Female sex                     |             | -0.14 (-1.05 to 0.78)  | 0.765            |
| BI                             |             | 0 (-0.13 to 0.02)      | 0.699            |
| Visit                          |             | -0.64 (-1.14 to -0.15) | <b>0.011</b>     |
| HAD (score)                    |             |                        |                  |
| SPC SU                         | 10.63 (1.7) |                        |                  |
| GRU                            | 8.64 (0.9)  | -1.99 (-5.87 to 1.89)  | 0.315            |
| Age (yrs)                      |             | 0.08 (-1.00 to 0.26)   | 0.379            |
| Female sex                     |             | -1.99 (-5.02 to 1.05)  | 0.200            |
| BI                             |             | -0.02 (-0.08 to 0.03)  | 0.383            |
| Visit                          |             | 1.46 (-0.45 to 3.38)   | 0.134            |

| Ten metre walk time (seconds) |              |                          |       |
|-------------------------------|--------------|--------------------------|-------|
| SPC SU                        | 53.35 (27.8) |                          |       |
| GRU                           | 39.61 (14.6) | -13.74 (-77.60 to 50.12) | 0.673 |
| Age (yrs)                     |              | 1.49 (-1.45 to 4.44)     | 0.320 |
| Female sex                    |              | -16.79 (-69.60 to 36.02) | 0.533 |
| BI                            |              | 0.25 (-0.64 to 1.14)     | 0.583 |
| Visit                         |              | 24.01 (-20.50 to 68.52)  | 0.290 |

**Data presented as median (SE); ^p value for t-test; SF36=; MCS=Mental component summary score; PCS=Physical component summary score; FIM=Functional independence measure; ARAT=Action Research Arm Test; BBS= Berg balance score; CMM= Chedoke McMaster; EQ5D VAS=European Quality of Life-5 Dimension Visual Analogue Scale; HAD=Hospital anxiety and depression score ; BI=Barthel Index score**

Table 6.4.8: Unadjusted outcome variable measures, mean scores (SE)

|                                 | SPC SU      |             | GRU         |             |
|---------------------------------|-------------|-------------|-------------|-------------|
|                                 | 6 months    | 12 months   | 6 months    | 12 months   |
| Primary variables:              |             |             |             |             |
| • SF36 MCS score                | 47.8 (2.8)  | 50.1 (2.8)  | 52.9 (1.6)  | 53.6 (1.6)  |
| • SF36 PCS score                | 39.4 (2.3)  | 47.1 (2.4)  | 36.4 (1.4)  | 41.6 (1.4)  |
| • FIM total score               | 106.2 (5.5) | 108.4 (5.5) | 97.2 (3.1)  | 97.0 (3.1)  |
| Secondary variables:            |             |             |             |             |
| • ARAT total score              | 96.0 (5.4)  | 104.7 (5.2) | 101.6 (3.0) | 99.0 (3.1)  |
| • Berg balance score            | 41.2 (4.3)  | 42.9 (4.3)  | 32.1 (2.4)  | 31.7 (2.4)  |
| • CMM shoulder inventory        | 4.1 (0.5)   | 4.7 (0.5)   | 4.6 (0.3)   | 4.8 (0.3)   |
| • CMM posture inventory         | 4.8 (0.3)   | 5.0 (0.3)   | 4.1 (0.2)   | 4.2 (0.2)   |
| • EQ5D VAS (centimetres)        | 6.8 (0.4)   | 6.8 (0.5)   | 5.9 (0.3)   | 6.8 (0.3)   |
| • HAD score                     | 9.5 (1.6)   | 8.1 (1.6)   | 9.7 (0.9)   | 8.2 (1.0)   |
| • Ten metre walk time (seconds) | 48.8 (32.9) | 19.6 (31.8) | 52.0 (17.6) | 30.4 (18.5) |

**Data presented as median (SE); ^p value for t-test; SF36=; MCS=Mental component summary score; PCS=Physical component summary score; FIM=Functional independence measure; ARAT=Action Research Arm Test; BBS= Berg balance score; CMM= Chedoke McMaster; EQ5D VAS=European Quality of Life-5 Dimension Visual Analogue Scale; HAD=Hospital anxiety and depression scale**

Table 6.4.9 Outcome variable measures, mean scores (SE) adjusted for age, gender, Barthel Index score and the repeated factor “visit” (6 month and 12 month follow up)

|                                 | SPC SU      |             | GRU         |             |
|---------------------------------|-------------|-------------|-------------|-------------|
|                                 | 6 months    | 12 months   | 6months     | 12 months   |
| Primary variables:              |             |             |             |             |
| • SF36 MCS score                | 48.8 (3.2)  | 51.1 (3.3)  | 53.6 (1.8)  | 53.7 (1.8)  |
| • SF36 PCS score                | 34.5 (2.5)  | 42.0 (2.6)  | 37.3 (1.4)  | 42.9 (1.4)  |
| • FIM total score               | 92.6 (5.6)  | 94.7 (5.6)  | 101.0 (2.8) | 99.8 (2.8)  |
| Secondary variables:            |             |             |             |             |
| • ARAT total score              | 91.3 (6.1)  | 100.4 (6.0) | 103.0 (3.2) | 101.1 (3.3) |
| • Berg balance score            | 27.7 (4.2)  | 29.4 (4.2)  | 35.2 (2.1)  | 34.8 (2.1)  |
| • CMM shoulder inventory        | 3.7 (0.5)   | 4.2 (0.5)   | 4.8 (0.3)   | 5.0 (0.3)   |
| • CMM posture inventory         | 3.9 (0.3)   | 4.0 (0.3)   | 4.3 (0.2)   | 4.3 (0.2)   |
| • EQ5D VAS (centimetres)        | 6.9 (0.5)   | 6.9 (0.6)   | 5.9 (0.3)   | 6.7 (0.3)   |
| • HAD score                     | 11.3 (1.9)  | 10.0 (1.9)  | 9.4 (1.0)   | 7.9 (1.1)   |
| • Ten metre walk time (seconds) | 67.9 (36.6) | 38.9 (36.0) | 50.8 (19.1) | 28.4 (20.1) |

**Data presented as median (SE); ^p value for t-test; SF36=; MCS=Mental component summary score; PCS=Physical component summary score; FIM=Functional independence measure; ARAT=Action Research Arm Test; BBS= Berg balance score; CMM= Chedoke McMaster; EQ5D VAS=European Quality of Life-5 Dimension Visual Analogue Scale; HAD=Hospital anxiety and depression scale**





## **CHAPTER 7**

### **Publication**

This chapter consists of a paper that has been submitted for publication. Because of the requirements of publication, the introduction and background section contain some repetition of information presented earlier in the thesis.

Title:

Where and how do stroke patients spend their time on a stroke unit compared to a geriatric rehabilitation unit?

## ABSTRACT

*Objective:* To observe where and how hospitalized stroke patients spend their time in a stroke rehabilitation unit (SU), compared with geriatric rehabilitation units (GRUs).

*Design:* Prospective observational study.

*Setting and Participants:* All inpatients at one SU and 3 GRUs within Perth metropolitan area, between 2002 and 2004. Patients with diagnosis of “stroke” were identified within the cohort.

*Intervention:* The location and behaviour of all inpatients was observed and recorded for 30 minutes on ten separate occasions over two consecutive days every eight weeks. In addition, the specific location and activities of up to four inpatients with stroke were monitored for 15 minutes on eight occasions over two days every eight weeks.

*Main Outcome measures:* Location was classified under 7 categories, relating to the physical layout of the unit. Behaviour was classified using 15 categories that were defined according to whether isolated or engaged, and active or inactive.

*Results:* Stroke inpatients on SU were more likely to be located in a therapy area (OR=9.41; 95%CI 7.58 to 11.68) and more likely to be actively engaged in rehabilitation (OR=3.77; 95%CI 3.24 to 4.38) than patients in a GRU who, in turn, were more likely to be located in bed (OR=4.01; 95%CI 3.47 to 4.64) and to be isolated rather than engaged (OR 2.90; 95%CI: 2.52-3.35). Analyses of individual mapping data of stroke patients adjusted for potential confounding of age and/or Barthel Index showed patients in GRUs spent significantly more time in the bedspace (Incidence Rate Ratio (IRR): 1.41; 95% CI: 1.01-1.98) and in isolated behaviour (IRR: 1.34; 95%CI: 1.04-1.72), and less time in active behaviour (IRR: 0.66; 95%CI: 0.45-0.98) than did patients in the SU.

*Conclusions:* There was a difference in the location and behaviour of patients undergoing rehabilitation in a SU compared to the GRUs. More research is needed to explore whether these differences have effects on functional outcome.

## Introduction

Stroke units improve outcome and reduce hospital stay without increasing therapy time (Kalra, Dale et al. 1993; Kalra, Evans et al. 2005). Retrospective analysis of the components of care in effective stroke rehabilitation units have identified at least two different types of stroke units (Langhorne, 2002). The dedicated neurological stroke unit (SU) provides care specifically for those patients with neurological disabilities including stroke, and the mixed assessment general rehabilitation unit exists within geriatric and general rehabilitation services. Both provide different forms of organized multidisciplinary coordinated care consistent with the basic definition of “stroke unit”, and both are associated with better outcomes for stroke patients compared to the care provided in a general medical ward (Stroke Unit Trialists' Collaboration 1997) or by a roving stroke rehabilitation team (Kalra, 2000). However, it is unknown whether the culture and ethos towards stroke rehabilitation is different between these two types of units, and whether these two types of units operate quite differently on a day-to-day basis. This study has sought to examine the culture and ethos of the units by quantifying the amount of time patients spend in different locations and the activity or behaviour they undertake during this time.

Behavioural mapping involves observational study whereby subjects are monitored for specific time periods during daily activities, and details of those activities or behaviours are recorded. It has been used since the 1970's to measure activity patterns, time usage, and thereby the culture and the functional organization of a facility [Keith, 1980; Keith, 1987; Fairbanks, 1977].

Early studies involving the observation of patients with stroke using behaviour mapping focused on the static time patients were seen in solitary behaviour,

treatment behaviour or social behaviour (Keith 1980; Lincoln, Gamlen et al. 1989; Tinson 1989). Other studies have looked at the specific activities undertaken at the time of observation (Ada, 1999; Bernhardt, 2007; Bernhardt, 2008; Bernhardt, 2004 ; Mackey, 1996 ; Newall, 1997). Overall, results have shown that formal therapy occupies only a small portion of patients' average day.

The purpose of this study was to observe if there were any differences between where and how patients with stroke spent their time in a SU, compared with three geriatric rehabilitation units (GRUs).

## Methods

### Ethics

Ethics approval was granted by relevant committees at all participating hospitals, and Curtin University. Ward staff and allied health professionals at each facility attended group information sessions conducted by the principal investigator and subsequently provided written consent to be observed with their patients on multiple occasions over 2 consecutive days between November 2004 and December 2006.

### Design and setting

A prospective observational cohort study was undertaken in one stroke rehabilitation unit (SU) and three geriatric stroke units (GRUs) within Perth metropolitan area between 2002 and 2004.

### Participants

Participants were inpatients of either the SU or one of three GRUs at the time of the surveys. Included in the cohort were disabled survivors of a recent acute stroke who were undergoing active inpatient rehabilitation, and all of these were identified as “stroke” patients during data collection. Some of this group were participating in another study documenting functional outcome of patients with stroke.

### Baseline data

Baseline data were collected from each unit regarding the characteristics of the ward, including numbers of therapy staff, daily routines, case-mix, floor-plan, bed numbers and infrastructure. Other descriptive data was also collected at baseline from the functional outcome stroke patient cohort. These data included age, gender and Barthel score on admission.

### Intervention

The location, behaviour and level of interaction of all patients on each of the rehabilitation units were observed on a rotation basis for 2 weekdays (Wednesday and Thursday) every 8 weeks, over 25 months between November 2002 and December 2004. This resulted in complete data from 51 visits (13 each at three facilities, and 12 at the other facility), and included a total of 13,360 patient observations, of which 4119 were stroke patient observations.

### Training

A single observer (physiotherapy assistant, JV) undertook the behaviour mapping who was trained (DD) and practiced in the use of the mapping forms for half a day at each facility prior to the study. A ward familiarization process involving consultation with incumbent ward staff at each facility was also undertaken, and this provided details of the day to day ward routines including room allocation system, patient treatment programming, and areas where treatment interventions were actually carried out. This enabled the observer to locate all ward patients efficiently on a 30-minute walk-through the ward and rehabilitation areas. This observer was not blinded to type of unit.

### Procedure

Two forms of mapping were conducted. The first was topographical. For this form of mapping a floor plan of the ward and treatment areas was utilised (Appendix 5). A routine was devised so that the observer was able to walk through the ward and

therapy areas 5 times each day at 9.00, 11.00, 13.00, 14.30 and 16.00 following a pre-planned path and visiting each room and treatment area. Thirty minutes was allowed for each sweep of the ward. This was sufficient time for all patients on the ward, regardless of their diagnosis, to be identified and their location and behaviour to be recorded on the map. When patients were away from the ward but their location was known (e.g. at the podiatrist or X-ray), this was noted. Their behaviour was not recorded, except if the interaction was known (e.g. one on one interaction with therapist). Therefore, for each patient there were potentially ten observation maps of their whereabouts and behaviour over 2 days.

The second form of mapping was patient-based (Appendix 2). For these maps, up to four patients with stroke who were participating in another study documenting the functional outcome of patients with stroke were identified for more detailed observation during the one-hour interval between the location-based sweeps. These patients were individually located and their behaviour observed for 15 minutes each. During this 15-minute period, behaviour was observed at 1-minute intervals and recorded. This provided 8 maps for each patient from a total of 2 hours of individual observations over the two days with a potential total of 32 individual maps from each facility over this time.

Prior to the commencement of data collection each day, the observer ascertained the number of inpatients and which of those had stroke and planned the order of individual patient observations so patients were not observed at exactly the same time each day (Appendix 3).

#### Categories of behaviour

Patient behaviour was defined as isolated or engaged with others, independent or dependent, and active or inactive. From previous research (Lincoln, 1989) and in other pilot work for this study relating to the performance of rehabilitation, a 15-point descriptive classification was devised (Table 1).

In this classification, there were 5 categories of “Isolated behaviour” that differentiated between disengaged behaviour in (1) and out of bed (2), whilst physically inactive (3), or active (4) and active independent self-maintenance (5). “Mid-Engaged behaviour” included independent activity in a group environment (6) and being transferred between activities (7). “Engaged behaviour” was defined by individual verbal interactive behaviour relating to medical, nursing or therapy staff (8) and individual or group interactions relating to visitors (9). There was also differentiation between behaviour involving a physical task relating to visitors (10), nursing or medical care (11) or therapy (12). Finally, in terms of groups and therapy behaviours, there were those behaviours related to a task group intervention by therapists (13), a verbal group intervention by multiple staff (14) or a patient group intervention related to a task (15). Specific examples of each behaviour are provided in Table 1.

During both forms of mapping, the location of the patient was documented on the floor plan, and this was classified into one of 7 categories (Table 2).

#### Statistical methods

Data were extracted from the topographical maps as counts. The number of patients in each location was summed across all sweeps of the ward. Similarly the numbers of patients participating in each behaviour were summed across all sweeps of the ward. For the patient-based mapping, each 1 minute interval was considered a count and the counts for each location and behaviour were summed across all 15 minute periods of observation.

Comparisons between SU and GRU of counts from topographical mapping were analysed using log linear analysis with robust standard errors due to repeated observations within patients. For the location mapping, two contrasts of interest were tested: “at the bedside” versus “all other areas” and “in a therapy area” versus

“all other areas”. For the behaviour mapping two contrasts of interest were tested: “isolated” versus “mid-engaged and engaged” and “active” versus “inactive”.

For the patient-based mapping, counts were summed for the locations “at the bedside” and “in a therapy area”, and for the behaviours “isolated” and “active”. Comparisons between SU and GRU of counts from patient-based mapping were made using four separate negative binomial regression models, accounting for differences between individuals in total observation minutes. Comparisons between SU and GRU were examined adjusting for age, sex and Barthel Index measured on hospital admission, and final multivariable models are presented where these variables displayed associations with the outcome variable at  $p < 0.200$ .

Data were analysed using Stata/IC 10.1 for Windows (StataCorp LP: College Station, TX). Statistical significance was set at  $\alpha = 0.05$ .

## Results

### Environment

All units were situated on the ground floor of the hospital and the characteristics of the ward environments are summarized in Appendix 4. The SU had no dining room and communal shower/ toilet facilities, and 74% of beds were within 4bed rooms. All GRUs had dining rooms, individual room shower/toilet facilities and 83-100% of beds with within single and double rooms.

Full time equivalent (FTE) staff numbers and ward routines are summarized in Appendices 4 and 5 respectively. The SU had a total of 8.2 FTE while the GRUs had 3.2 (mean total, range 2.2 to 3.9) FTE. All units had equivalent meal breaks and comparable length of ward rounds, and rest periods. The SU had no formal ward meetings or group sessions on survey days, and visiting hours were more restricted and enforced compared with the GRUs.



## Case mix

A higher proportion of SU case mix was stroke, such that 2689 (81.7%) of the total 3291 patient observations were of stroke patients compared with 1430 (14.2%) of the total 10069 patient observations at the GRUs (Appendix 4).

## Mapping

### Topographical data

Overall patients in GRU and SU were found in different locations ( $p < 0.001$ ). The number (percentage) of observations in each location at both units is shown in Table 2. Of the 10,069 observations from GRU, 7,024 (69.8%) were at the bed space, whereas of the 3,291 observations from the SU, only 1,258 (38.2%) were at the bed space. Therefore, compared with patients in the SU patients in the GRU were more likely to be located in the bed space than anywhere else on the ward (OR 3.72, 95%CI 3.42 to 4.06,  $p < 0.001$ ) (Table 2). Of the 10,069 observations from GRU, 694 (6.9%) were in a therapy location, compared to 1,366 of 3,291 (41.5%) observations from the SU. Therefore, patients in the SU were more likely than patients in the GRU to be located in a therapy area than anywhere else on the ward (OR=9.59; 95%CI 8.55 to 10.74,  $p < 0.001$ )(Table 2). A similar pattern was observed in patients with stroke being more likely to be found in the bed space in the GRU (OR=4.01; 95%CI 3.47 to 4.64,  $p < 0.001$ ) and in therapy areas in the SU (OR=9.41; 95%CI 7.58 to 11.68,  $p < 0.001$ )(Table 2).

Overall patient behaviours differed between GRU and SU ( $p < 0.001$ ). The number and percentage of observations for each behaviour in both units is shown in Table 3. Of the 9875 observations of behavior from the GRU, 7,114 (72.0%) were of isolated behavior, compared to 1,338 of the 3,245(41.2%) observations in the SU. Compared with patients in the SU patients in the GRU were more likely to be isolated than engaged (OR3.67; 95% CI 2.37 to 4.00,  $p < 0.001$ ). Furthermore, 1,855 of 3,245 (57.2%) observations from the SU were of active behaviour, compared to 2,547 of 9,875 (25.8%) observations from the GRU. Patients in the SU were more

likely to be active than patients in the GRU unit (OR=3.84; 95%CI 3.52 to 4.19,  $p<0.001$ ). A similar pattern was observed in patients with stroke being more likely to be isolated in the GRU (OR=2.90; 95%CI 2.52 to 3.35,  $p<0.001$ ) and patients are more likely to be active in the SU (OR=3.77; 95%CI 3.24 to 4.38,  $p<0.001$ ).

#### Patient based data

Characteristics of the 51 patients with stroke that were individually located and observed for 15 minute periods are displayed in Table 4. Patients in the SU were significantly younger than those in the GRUs but were comparable with regard to Barthel Index and sex (Table 4). The results of the univariable and multivariable negative binomial regression analyses are displayed in Table 5. Patients in GRUs spent significantly more time in the bed space (adjusted Incidence Rate Ratio (IRR): 1.41; 95% CI: 1.01-1.98,  $p=0.045$ ) and in isolated behaviour (adjusted IRR: 1.34; 95%CI:1.04-1.72,  $p=0.021$ ), and less time in active behaviour (adjusted IRR: 0.66; 95%CI:0.45-0.98,  $p=0.039$ ) than did patients in the SU. There were no significant differences observed in time spent in therapy areas between SU and GRUs (Table 4).

#### Discussion

This is the first published study that reports whether stroke patients in a dedicated SU staffed by neurologists spend time in different locations and exhibit different behaviours to stroke patients in mixed GRUs staffed by geriatricians. The study examined the differences between units by both topographical and patient-based mapping.

#### Topographical mapping of location and behaviour

Overall, SU patients were more likely to be in a rehabilitation-specific area (gymnasium, occupational or speech therapy areas) and less likely to be in the bed space compared to GRU patients. There was also a difference in frequencies of patient behaviours between GRU and SU ( $p<0.001$ ) whereby SU patients were less

isolated (behaviours 1 to 5 in table 1) and more active (behaviours 4, 5, 6, 11, 12, 13 and 15 in table 3) than GRU patients.

The fact that SU were more likely to be found in the gymnasium or other therapy areas may have been a direct result of a SU culture whereby patients were encouraged to be out of their rooms and attending rehabilitation, or at least be located in the rehabilitation area, observing other patients undergoing treatment. A comparatively larger SU gymnasium, able to contain more people may have enabled this difference.

A recent Australian study found that acute stroke patients in acute SUs spend a lot of time resting in bed (Bernhardt, Dewey et al. 2004), but in our sub-acute study, this was more evident in the GRUs than in the SU. The relatively smaller therapy areas in the GRUs may in part explain the fact that GRU patients were more likely to be found in the bed space. It is possible that the single and double bed spaces of the GRUs afforded relatively more space than the communal gymnasiums, and also supported a GRU culture that enabled private socialization with visitors.

The fact that SU patients were less isolated may also have been a direct result of the different room configuration of each type of facility, whereby there was a higher proportion of single bedrooms in the GRUs compared with the SU. The SU gymnasium was also significantly larger than any of the GRU gymnasiums, and was therefore conducive to fitting multiple people into the space. This may have potentiated relatively more patient/therapist and patient/patient interaction in the SU.

In addition to the comparisons made between units, this study has also shown that overall, sub-acute stroke patients spend a large proportion of their time alone and this is consistent with other observational studies of stroke patients (Keith 1980; Lincoln, Gamlen et al. 1989; Tinson 1989).

The fact that patients on the SU were more likely to be engaged in activity either by themselves or in a group setting is important in the context of effective rehabilitation. It has been stated previously that in order to maximize physical recovery from stroke, rehabilitation units should be structured so that patients are challenged to repeatedly practice the motor skills they are unable to perform (Mackey, 1996). It may be that the SU model potentiates a culture of exercise and participation as patients are more active, even when they are alone.

#### Patient-based mapping

##### Association of patient-level factors with study outcome

Patient-based mapping of locations and behaviours allowed differences between units to be adjusted for potential patient-level factors. Age was significantly associated with bed space location, isolated and active behaviour. Older patients with stroke were more likely to be in the bed space and isolated, and less likely to be involved in active behaviour. This finding could be interpreted to be consistent with other studies that older age is associated with inferior care for patients with stroke (Palnum KD, Petersen P et al. 2008; Luker, Wall et al. 2011). However, not all studies demonstrate associations between age and quality of stroke care (Luker, Wall et al. 2011) and others have reported that age proxies such as stroke severity and higher levels of comorbidity may be stronger predictors of whether recommended care is provided (Luker, Wall et al. 2011).

Gender was not significantly associated with bed space location, therapy area location, isolated or active behaviour. This lack of sex-related difference is also consistent with the literature (Palnum, Andersen et al. 2009).

Patients with a higher Barthel score, indicating greater functional independence, were more likely to be isolated. This suggests that more able patients are less dependent upon and therefore less interactive with staff, whilst less able patients require more assistance and thereby are more engaged with staff.

#### Patient-based location

The results of the patient-based analysis was consistent with the topographical mapping with regard to the finding that the GRU patients were more likely to be in the bed space, and this association remained statistically significant after adjusting for age. This suggests that the differences in cultural values of each type of unit (with emphasis placed on rehabilitation versus socialization with visitors) remain regardless of the indication for admission (treatment of stroke or other pathology) within the cohort.

The results of the patient-based analysis were inconsistent with the topographical mapping with regard to the finding that the patient-based mapping did not confirm the finding from the topographical mapping that patients in the SU were more likely to be found in a therapy area than patients in GRUs. It may be that topographical mapping captured a broader range of functionally dependent stroke patients, in whom treatment priorities differed, (whether socialization over rehabilitation, or vice versa) compared with the much smaller population enrolled in the functional outcome study (where rehabilitation may have been prioritized, see limitations section).

#### Patient-based behaviour

The results of the patient-based analysis was consistent with the topographical mapping with regard to the finding that GRU patients were more likely than SU patients to be engaged in isolated behaviour, with this association remaining statistically significant after adjusting for age and Barthel Index. Similarly, the results of the patient-based analysis was consistent with the topographical mapping with regard to the finding that SU patients were more likely than GRU patients to be engaged in active behaviour, with this association remaining statistically significant after adjusting for age. These findings support the premise that no matter what the admission age and diagnosis (and for some factors, the level of dependency), patients

will exhibit different behaviours according to whether they are admitted to a GRU or a SU.

#### Unit-based factors

The fact that only one SU was included prevented any statistical evaluation of the contribution of unit-based factors to the explanation of the differences in location and behaviour observed. Some unit-based factors that are potentially explanatory are staffing and the opportunity for social support within the facility.

#### Staffing

The SU had between 2 and almost 4 times the staffing levels of the GRUs across physiotherapy, occupational therapy and speech therapy. Higher staffing levels may be conducive to a more rehabilitation-focused culture whereby patients are less likely to be bed or bedroom-bound and more likely to be in therapy areas.

It has also been found that in well staffed and resourced units, patients still received little therapy and had low levels of physical activity (Mackey, Ada et al. 1996; Bernhardt, Chan et al. 2007). A relative lack of spontaneous activity is a pervasive feature of the behaviour of institutionalized people, and is important in view of the likely relationships between inactivity and both depression and physical deterioration (Burton 1980). Whether the level of interaction demonstrated here translates to better or worse functional recovery is also beyond the scope of this study and remains questionable considering that another study has estimated more than half of the time stroke subjects spent in therapy was undertaking activity unrelated to physical outcome (58%), while only one third was task practice (34%) and minimal time was spent exercising (8%) (Ada 1999).

#### Social support

Studies have shown that the support of family and friends is important to improved functional outcome and that high levels of social support is associated with faster and

more extensive recovery (Kwakkel, Wagenaar et al. 1996) and that socially isolated patients may be at particular risk for poor outcome (Glass, Matchar et al. 1993). It was interesting to note that GRU patients spent more time interacting with visitors than those in the SU. This most likely related directly to the culture of the unit, whereby visitors were able to access patients for longer periods throughout the day, but may also be a reflection on the central location of the SU, and the satellite nature of the GRUs that were generally located closer to the homes of resident inpatients.

Whether these environmental differences impacted on functional recovery from stroke is beyond the scope of this study. A randomized controlled trial of a cohort equally suited for rehabilitation in either facility is needed to explore the effect of the environmental differences found here on functional outcome after rehabilitation.

#### Study Strengths and Limitations

A limitation of the study was that although there was an established difference in the proportion of stroke patients between the SU and GRUs, only a small proportion of the cohort had data that defined their age, gender and dependency (baseline Barthel score). It is likely that while some of the stroke patients were comparable between the two different settings, other stroke and non-stroke patients had large differences in dependency levels and the potential for aggressive rehabilitation. Higher dependency levels and other comorbid conditions in GRUs may explain differences in the location and behaviour of patients at these facilities.

Another limitation of the study was that of observer bias, as the mapping assessor could not be blind as to the rehabilitation unit. This potential bias was minimized by uniform data collection, such that there were well defined criteria for classifying locations and behaviours, careful preparation of topographical maps and rigorous training of the assessor at each research site prior to data collection.

A strength of the study was that there was one assessor across all units.

## Conclusion

This study has demonstrated a difference in the location and behaviour of patients undergoing rehabilitation for stroke in a neurological stroke unit compared to three geriatric rehabilitation units, after adjustment for patient age and dependency. More research is required to measure whether or not these differences impact on long term functional outcome, whether cost in terms of resource use and length of stay are different between type of facility, and whether improved outcome might justify cost differences.

## ACKNOWLEDGEMENTS

The authors gratefully acknowledge the following:

Jill Vinton (JV) for her assistance in data collection

Rose Wyllie (RW) for her technical help to design and pilot ward maps and routines

Jo Bouckley (JB) for her general collaboration

The staff and patients observed at participating hospitals



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## Tables and Figures

Table 1: Categories of Behaviour

| ISOLATED BEHAVIOUR    |   |   |
|-----------------------|---|---|
| 1                     | Isolated disengagement, with patient in or on the bed | staring into space, asleep                      |
| 2                     | Isolated disengagement, with patient out of bed       | staring into space, asleep                      |
| 3                     | Inactive individual task                              | watching television, reading                    |
| 4                     | Active individual task                                | practicing exercises by them self               |
| 5                     | Independent self maintenance                          | independent toileting, showering, or self-care  |
| MID-ENGAGED BEHAVIOUR |   |   |
| 6                     | Independent activity in a group environment           | practicing exercises indep in a gym with others |
| 7                     | Transferring between activities by staff              |   |

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## ENGAGED BEHAVIOUR

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|    |   |  |
|----|---|--|
| 8  | Individual interaction that is verbal only                      | talking to individual patient, one on one          |
| 9  | Individual or group interaction that is verbal and social       | non-ambulant interaction with visitors             |
| 10 | Individual or group interaction that is associated with a task  | visitors who take patients for a walk              |
| 11 | Individual interaction with task, related to self care          | Eg one nurse assisting with showering or toileting |
| 12 | Individual interaction with task, related to therapy staff      | shower assessment with occupational therapist      |
| 13 | Therapist group interaction involving task                      | 2 therapists undertaking gait retraining           |
| 14 | Group interaction that is verbal only relates to care           | family meeting                                     |
| 15 | Patient group interaction with a task, related to therapy staff | group exercise class                               |

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Table 2: Location of patients on ward, utilizing Topographical-based mapping

|                    | All patients mapped<br>during 30 minute whole ward sweep*<br>N, (% observations) |             | P-value | Stroke patients mapped<br>during 30 minute whole ward sweep**<br>N, (% observations) |            | P-value |
|--------------------|--|-------------|---------|--|------------|---------|
|                    | GRU  | SU          |         | GRU  | SU         |         |
| Bed space          | 7024 (69.8)  | 1258 (38.2) |         | 977 (68.3)   | 940 (35.0) |         |
| Gymnasium          | 209 (2.1)  | 1036 (31.5) |         | 44 (3.1)   | 972 (36.2) |         |
| Other therapy area | 485 (4.8)  | 330 (10.0)  |         | 80 (5.9)   | 297 (11.0) |         |
| Day room           | 606 (6.0)  | 40 (1.2)    |         | 99 (6.9)   | 34 (1.3)   |         |
| Outside            | 290 (2.9)  | 170 (5.2)   |         | 43 (3.0)   | 117 (4.4)  |         |
| Shower/ toilet     | 610 (6.1)  | 247 (7.5)   |         | 103 (7.2)  | 164 (6.1)  |         |
| Dining Room        | 347 (3.4)  | 2 (0.1)     |         | 35 (2.4)   | 2 (0.1)    |         |
| Hallway            | 498 (5.0)  | 208 (6.3)   | <0.001  | 49 (3.4)   | 163 (6.1)  | <0.001  |

\* Based on 13360 weekday observations (52 observation periods x 2 days per period x number of patients on ward during that observation day); \*\* Based on 4119 weekday observations (52 observation periods x 2 days per period x number of Stroke patients on ward during that observation day)

Table 3: Behaviour of patients on ward, topographical mapping method

|                          | All patients mapped<br>during 30 minute whole ward<br>sweep* |            | Stroke patients mapped<br>during 30 minute whole ward<br>sweep** |            |
|--------------------------|--|------------|--|------------|
|                          | N (% observations)   |            | N (% observations)   |            |
|                          | GRU  | SU         | GRU  | SU         |
| Isolated behaviour^      |  |            |  |            |
| 1 (inactive)             | 2393 (24.4)  | 255 (7.9)  | 317 (22.9)   | 184 (7.5)  |
| 2 (inactive)             | 2106 (21.3)  | 299 (9.2)  | 294 (21.2)   | 234 (9.6)  |
| 3 (inactive)             | 1446 (14.6)  | 366 (11.3) | 197 (14.2)   | 264 (10.8) |
| 4 (active)               | 610 (6.2)  | 201 (6.2)  | 48 (3.5)   | 156 (6.4)  |
| 5 (active)               | 559 (5.7)  | 217 (6.7)  | 62 (4.5)   | 148 (6.1)  |
| Mid- engaged behaviour^^ |  |            |  |            |
| 6 (active)               | 67 (0.7)   | 702 (21.6) | 15 (1.1)   | 492 (20.2) |
| 7 (inactive)             | 50 (0.5)   | 64 (2.0)   | 4 (0.3)  | 51 (2.1)   |

|                             |             |             |             |             |
|-----------------------------|-------------|-------------|-------------|-------------|
| Engaged behaviour^^         | 279 (2.8)   | 79 (2.4)    | 36 (2.6)    | 56 (2.3)    |
| 8 (inactive)                | 945 (9.6)   | 282 (8.7)   | 149 (10.8)  | 200 (8.2)   |
| 9 (inactive)                | 69 (0.7)    | 25 (0.8)    | 12 (0.9)    | 21 (0.9)    |
| 10 (inactive)               | 633 (6.4)   | 191 (5.9)   | 123 (8.9)   | 136 (5.6)   |
| 11 (active)                 | 341 (3.4)   | 516 (15.9)  | 76 (5.5)    | 458 (18.8)  |
| 12 (active)                 | 29 (0.3)    | 23 (0.7)    | 5 (0.4)     | 19 (0.8)    |
| 13 (active)                 | 40 (0.4)    | 20 (0.6)    | 4 (0.3)     | 15 (0.6)    |
| 14 (inactive)               | 308 (3.1)   | 5 (0.2)     | 42 (3.0)    | 5 (0.2)     |
| 15 (active)                 |             |             |             |             |
| Total isolated behaviour    | 7114 (72.0) | 1338 (41.2) | 918 (66.3)  | 986 (40.3)  |
| Total mid-engaged behaviour | 117 (1.2)   | 766 (23.6)  | 19 (1.4)    | 543 (22.3)  |
| Total engaged behaviour     | 2644 (26.8) | 1141 (35.2) | 447 (32.3)  | 910 (37.3)  |
| Total active behaviour      | 2547 (25.8) | 1855 (57.2) | 371 (26.8)  | 1414 (58.0) |
| Total inactive behaviour    | 7328 (74.2) | 1390 (42.8) | 1013 (73.2) | 1025 (42.0) |

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Table 3: Behaviour of patients on ward, topographical mapping method

\* Based on 13120 weekday observations (52 observation periods x 2 days per period x number of patients on ward during that observation day)

\*\* Based on 3823 weekday observations (52 observation periods x 2 days per period x number of Stroke patients on ward during that observation day)

^1= Isolated disengagement in/on bed; 2=Isolated disengagement out of bed; 3= Inactive individual task; 4=Active individual task; 5=Independent self maintenance

^^6= Independent activity in a group environment; 7=Being transferred between activities

^^^8= Individual verbal interaction with nursing, medical or therapy staff; 9= Individual or group verbal interaction with visitors/friends; 10= Individual or group physical task interaction with visitors/friends; 11=Individual interaction with task related to medical or nursing self care; 12= Individual interaction with staff related to therapy staff; 13= Therapist group interaction involving task; 14= Group interaction which is verbal and relates to nursing, medical or therapy staff; 15= Patient group interaction with a task related to therapy staff



Table 4: Characteristics of individually mapped stroke patients\*\*\*

|                  | SU<br>N=15    | GRU1<br>N=8 | GRU2<br>N=10 | GRU3<br>N=18 | P-value |
|------------------|---------------|-------------|--------------|--------------|---------|
| Age (yrs)        |               |             |              |              | <0.001  |
| Mean(SD)         | 62.9<br>(3.5) | 78.8 (7.2)  | 79.5 (8.8)   | 75.4 (7.9)   |         |
| Min-max          | 60.3-73.0     | 66.0-88.7   | 67.3-91.0    | 64.0-92.3    |         |
| Female sex, N(%) | 3 (20.0)      | 3 (37.5)    | 5 (50.0)     | 6 (33.3)     | 0.541   |
| Barthel Index    |               |             |              |              | 0.903   |
| Median (IQR)     | 25 (55)       | 10 (20)     | 12 (50)      | 20 (42)      |         |
| Min-max          | 0-95          | 0-95        | 0-75         | 0-75         |         |

\*\*\* Based on a total of 8460 minutes hours of observation (52 observation periods x 2 days per period x up to 4 stroke patients on ward during that observation day)

Table 5: Unadjusted and Adjusted Incidence Rate Ratios from negative Binomial Regression Analysis unadjusted and adjusted for potential confounding factors

|                            | Unadjusted IRR<br>(95% CI) | p-value | Adjusted IRR<br>(95% CI)      | p-value |
|----------------------------|----------------------------|---------|-------------------------------|---------|
| Bed space location         |                            |         |                               |         |
| SU                         | 1.00                       |         | 1.00                          |         |
| GRU                        | 1.52 (1.20-1.93)           | 0.001   | 1.41 (1.01-1.98)              | 0.045   |
| Age (yrs)                  | 1.02 (1.00-1.03)           | 0.008   | 1.01 (0.99-1.02)              | 0.515   |
| Female sex                 | 1.07 (0.82-1.39)           | 0.635   |                               |         |
| Barthel Index <sup>1</sup> | 1.02 (0.97-1.06)           | 0.438   |                               |         |
| Therapy area location      |                            |         |                               |         |
| SU                         | 1.00                       |         | 1.00                          |         |
| GRU                        | 0.55 (0.22-1.40)           | 0.210   | 0.55 <sup>2</sup> (0.22-1.40) | 0.210   |
| Age (yrs)                  | 0.98 (0.94-1.02)           | 0.396   |                               |         |
| Female sex                 | 1.20 (0.46-3.16)           | 0.706   |                               |         |
| Barthel Index <sup>1</sup> | 1.07 (0.92-1.25)           | 0.383   |                               |         |
| Isolated behaviour         |                            |         |                               |         |
| SU                         | 1.00                       |         | 1.00                          |         |
| GRU                        | 1.58 (1.30-1.91)           | <0.001  | 1.34 (1.04-1.72)              | 0.021   |
| Age (yrs)                  | 1.02 (1.01,1.03)           | <0.001  | 1.01 (1.00-1.02)              | 0.062   |
| Female sex                 | 1.11 (0.89-1.39)           | 0.363   |                               |         |
| Barthel Index <sup>1</sup> | 1.04 (1.00-1.08)           | 0.029   | 1.04 (1.01-1.07)              | 0.009   |
| Active behaviour           |                            |         |                               |         |
| SU                         | 1.00                       |         | 1.00                          |         |
| GRU                        | 0.51 (0.39-0.69)           | <0.001  | 0.66 (0.45-0.98)              | 0.039   |
| Age (yrs)                  | 0.97 (0.95-0.98)           | <0.001  | 0.98 (0.96-1.00)              | 0.043   |
| Female sex                 | 0.86 (0.61-1.22)           | 0.398   |                               |         |
| Barthel Index <sup>1</sup> | 1.00 (0.95-1.06)           | 0.917   |                               |         |

Table 5: Unadjusted and Adjusted Incidence Rate Ratios from negative Binomial Regression Analysis unadjusted and adjusted for potential confounding factors

<sup>1</sup>Incidence Rate Ratio for an increase in 10 points in Barthel Index

<sup>2</sup>Univariable estimates only as neither age, sex or Barthel were identified as potential confounders

\*\*\* Based on a total of 8460 minutes hours of observation (52 observation periods x 2 days per period x up to 4 stroke patients on ward during that observation day)



## CHAPTER 8

### Discussion

#### 8.1 Introduction

Stroke is a significant cardiovascular event requiring sub-acute rehabilitation, best provided in a SU (Stroke Unit Trialist's Collaboration 1997; Stroke Unit Trialists' Collaboration 2007; Hankey and Warlow 1999). Patient factors such as age and social network may influence the choice of facility best suited for an individual to undergo rehabilitation. Stroke units include dedicated neurological SUs usually catering only for patients with stroke and more generic SUs existing within geriatric rehabilitation units (GRUs). Both are associated with better outcomes for patients with stroke than care in general medical wards (Foley, Teasell et al. 2003). In Perth both types of units are available for patients requiring sub-acute rehabilitation.

The studies comprising this thesis have recruited from patients with acute stroke admitted to RPH-WSC. In addition, the operation of four facilities where this group of patients are routinely referred for sub-acute rehabilitation have been considered in detail. The four facilities include one dedicated neurological SU and three GRUs. The patients of particular interest were those for whom the decision regarding the optimal type of rehabilitation SU facility was arbitrary, enabling a direct comparison between the two rehabilitation models for this group of stroke survivors. In the thesis the differences in the intensity of rehabilitation at each type of facility, the staffing resources and approaches to rehabilitation have been considered in relation to the benefits in terms of physical and emotional outcomes of patients at 6 and 12 months post-stroke. To our knowledge, no previous studies have directly compared the outcomes of patients attending the two types of sub-acute stroke units that have been the focus of the studies presented in this thesis.

## 8.2 Major findings

### 8.2.1 Overview

In preliminary studies a number of differences were identified between facilities in terms of the intensity of rehabilitation, staffing resources and ward ethos in terms of with whom and where patients spend most of their time. In brief, there was a perception that the intensity of rehabilitation and staffing resources were greater at SPC SU than the GRUs. There were also differences in patient behaviour and location of patients in the different types of facilities. In the GRUs patients were more likely to be in isolated locations and unengaged than those in SPC SU. Despite this, there were few differences in outcomes for patients attending the different types of facilities. After adjustment for four potential confounding variables there were no detectable differences in outcome between the two groups of patients. While considering these findings it is important to recall that the patient group of interest were those patients of intermediate age who had the potential for sufficient recovery to return to independent living and the physical capacity to participate in intensive rehabilitation. These patients have been described as a “grey” group as there is no objective evidence indicating whether they should attend a more intensive SU or whether they would do as well with rehabilitation attending a GRU.

### 8.2.2 Patient recruitment and characteristics

Baseline data collected from the cohort were comprehensive as they were considered important both to establish the underlying level of disability and to be used as covariates in data analysis. The differences between groups at baseline were that patients referred to SPC SU were younger, more likely to be male, more likely to have abnormal language, more likely to have peripheral vascular disease and more likely to have diabetes.

Considering that age-specific ceilings are applied to all admissions to SPC SU, it was not surprising that there were a higher number of younger patients in this group. It

was an important difference to identify and adjust for however, because the evidence for an association between increasing age and poorer outcome is controversial in the literature and older age has been associated with inferior care for patients with stroke (Palnum KD, Petersen P et al. 2008; Luker, Wall et al. 2011).

In terms of gender, although the Perth Community stroke study reported equal gender distribution for stroke overall (Islam, Anderson et al. 2008), other studies have suggested that women are more globally older than men at stroke onset (Xiao-ying Yao 2012). It fits therefore that the younger SPC SU cohort were male dominant. Differences in gender distribution may be important as women have demonstrated poorer outcomes both in terms of disability and rate of institutionalization compared to men (Petrea, Beiser et al. 2009).

During the weekly ward meetings where rehabilitation options for current inpatients were discussed for the RCT SRO study design, one of the reasons provided by ASU staff as to why particular patients should be transferred to SPC SU rather than a GRU was the extent of speech therapy services available (see Chapter 5 *section 5.2.5*). There was a perception amongst staff in the acute SU at RPH-WSC that more extensive speech therapy rehabilitation was available at SPC SU compared to the GRUs as a whole. Data collected during behaviour mapping (see Chapter 7, Results and *Appendix 4*) supported this in terms of FTE staffing across sites. It follows that significantly more SPC SU patients had abnormal language at baseline, having been transferred specifically for more intensive speech therapy intervention.

The explanation for the significantly different incidence of past history of diabetes and peripheral vascular disease at SPC SU is more difficult, as one might expect these co-morbidities to be associated with the significantly older GRU cohort - although this assumption may or may not be true in a population of patients with stroke. Diabetes, peripheral vascular disease and hypertension share many predisposing vascular risk factors and often occur together. The fact that there was

no significant difference in the rate of past history of hypertension between groups, yet significant differences in the other 2 variables may reflect a Type I error in analyses of multiple baseline measures. In addition, although there are statistically significant differences, for peripheral vascular disease at least, the overall incidence is very small (6% of the whole cohort), and results should be interpreted with this in mind.

In terms of describing the whole “grey” cohort, most patients had previously lived independently (with or without partner) and this was not unexpected, given the common clinical history of stroke whereby there is a sudden deterioration in a previously high functioning individual (Bamford, Sandercock et al. 1991). Of interest is the fact that 44% of the grey group were present or past-smokers. This proportion is below that reported in a recent Australian study of young (less than 50 years of age) stroke survivors (Phillips, Leyden et al. 2011) and like-European data (von Sarnowski, Putaala et al. 2012) which found smoking to be a strong predictor of stroke.

In the majority of patients the stroke pathology was ischaemic (see Chapter 2, *section 2.1*) and in terms of stroke type, there was a higher number of PAC compared to LAC and TAC infarcts, and only a small number of POC infarcts. The fact that there were no differences in stroke type was important, given the literature that describes better outcome in some subtypes, particularly TAC stroke (Stone, Allder et al. 2000). Along with a predominant history of hypertension (72% of the whole cohort) these findings were consistent with other published data on stroke (Hallström, Jönsson et al. 2008; O'Donnell, Xavier et al. 2010).

On admission, overall mean Rankin (4), Barthel (34.8), Berg balance (17.03), Chedoke McMaster (shoulder 3; posture 3) and Scandinavian stroke scores (prognostic 16.3; long term 24.9) reflected a dependent population with considerable handicap, in keeping with the requirement for rehabilitation. Mean MMSE score



(21.7) suggested that cognitive impairment was not a characteristic of the cohort, and this is consistent with study exclusion criteria for dementia and confusion.

### 8.2.3 Outcome measures and covariates

Of the 10 unadjusted patient outcomes measured in this study, there were significant differences between groups in only two, the Berg balance score and the Chedoke McMaster posture inventory. The differences in both of these secondary outcomes favoured the SPC SU group. In addition there were differences in the SF36 MCS and PCS scores that approached significance. The difference in the PCS scores also favoured the SPC SU group but for the MCS score the GRU group had more favourable scores.

Median LOS data suggests that most follow-up appointments were undertaken after the patients had been discharged from rehabilitation, with the majority of patients returning to their own home. Within facility comparison indicated that SPC SU patients showed some improvements in most measures between 6 and 12 months, compared to GRU patients who improved in some measures and deteriorated in others. Although longitudinal data was not collected past 12 months, it may be that these differences would have increased over time, resulting in better long term outcomes for the SPC SU group.

Overall, scores reflected a relatively disabled population, requiring assistance with the more demanding aspects of activities of daily living. Raw scores were then adjusted using the covariates of age, gender, BI score and visit (whether 6 or 12 months). The choice of covariates was made on a pragmatic basis, and the same covariates were applied to all dependent variables.

Both age (Granger, Hamilton et al. 1992; Bagg, Pombo et al. 2002; Black-Schaffer, Winston et al. 2004; Kammergaard, Jørgensen et al. 2004; Calmels, Defay et al. 2005) and gender (Petrea, Beiser et al. 2009) may independently predict outcome,

and they were chosen as there were significant differences between facility type at baseline. In addition, age was a selection criterion for SPC SU patients. Although both were added as covariates, only age was significant for some variables.

Stroke severity has been found to predict both functional outcomes and the level of care provided (Luker, Wall et al. 2011), so a functional scale was also needed in case there were differences at baseline that carried through to 6 and 12 months. Although it would have been ideal to measure and collect the FIM score at baseline (with its sensitivity and lack of ceiling effect), RPH-WSC staff routinely used the BI to measure dependency in the acute setting, so these data were collected and used for baseline adjustment between facility type.

In reviewing results, it is important to remember that this “grey” stroke-survivor cohort represented only a small proportion of the total Perth stroke population (see Chapter 6, *section 6.2*), and that comparing data to other more inclusive populations of stroke patients should be done with caution. The sample recruited represented 26.5% of the population of patients meeting the selection criteria for the study during the period of recruitment. While it would have been ideal to recruit a larger sample this proportion is higher than that reported in other clinical studies of stroke cohorts (Anderson 2000).

#### 8.2.3.1 Quality of life, anxiety and depression

The SF36 scores presented were normalised to a healthy population so that a score of 50 represents the average score for a healthy population. Results for both the SF36 and the EQ5D VAS scores suggested no significant differences between patients according to facility type either before or after adjustment for covariates. In addition, changes to the SF36 MCS and the EQ5D VAS scores after adjustment were small. Level of patient anxiety and depression was also not influenced by where rehabilitation took place as HAD data showed no significant difference between facility before adjustment for covariates, and even less difference after adjustment.

Visit was the only covariate that predicted the EQ5D VAS score with higher scores at 12 months.

Overall SF-36 MCS (mean 52.3) scores reflect a population who perceived the mental health component of their quality of life as being just above average for a healthy population. These data are consistent with other published SF-36 data from stroke cohorts similar in terms of age, function (as defined by BI) and cognitive ability as defined by MMSE score (Anderson 2000). Other studies of more inclusive stroke populations have demonstrated that a substantial proportion of stroke-survivors have very poor quality of life outcomes (Haacke, Althaus et al. 2006). It would have been interesting to know the patients' perceived quality of life at baseline as it may be associated with their quality of life before and after rehabilitation. However, it was considered that measurement so soon after admission to hospital with an acute neurological event would confound the validity of the data.

Despite significantly different environments encompassing different rehabilitation ethos in terms of treatment goals and expectations, determined by behaviour mapping (see Chapter 7), the individual's sense of well-being and quality of life post-stroke did not differ between groups. This may reflect the fact that though different, the goals and expectations of both groups had been met during rehabilitation. For example, as the GRU cohort were geographically closer to their own homes, they received more socialisation (as demonstrated in the behaviour mapping data, Chapter 7) and this has been shown to be an important factor in successful rehabilitation without depression (Carod-Artal, Egido et al. 2000). The SPC SU cohort was exposed to a culture of intense treatment (see Chapter 6, *section* and Chapter 7), and their higher rate of interaction during therapy time may have been an important factor in their positive sense of well being. A worse quality of life outcome may have resulted in circumstances where the patient's expectations of the rehabilitation environment did not match their experience, whereby they perceived that they had been transferred to a poor quality facility. Exploring this notion was

irrelevant in the present study, as quality of life and level of anxiety and depression were close to that of healthy Australians.

Quality of life assessment is multidimensional and should consider physical, functional, psychological and social health. Both depression and disability have been found to be the strongest predictors of overall quality of life (Carod-Artal, Egido et al. 2000), with disability a stronger predictor of low quality of life than depression at 12 months. The finding of SF36 PCS scores lower than those of a healthy normal population is consistent with the other functional outcome measures used in the study that define the disability of the groups, and discussion of these follows. In multivariate models, BI, visit and age all predicted the SF36 PCS score and this is consistent with published data relating to increasing disability and health problems in older age (Haacke, Althaus et al. 2006) and therefore over time.

The finding of little anxiety and depression in the cohort is also in contrast to previous more inclusive population studies of stroke-survivors that have demonstrated that depression is a common characteristic post-stroke occurring in up to 60% of stroke survivors at 6 months post-stroke (Robinson, Starr et al. 1984; Robinson, Bolduc et al. 1987). The same studies demonstrated a correlation between the severity of the functional impairment, increasing age, the quality of social supports available, and the severity of depression. Similarly, generalised anxiety disorder after stroke has been reported as being common, long lasting and with the potential to impact substantially on functional recovery and outcome (Astrom 1996).

Mean HAD total score (8.9) overall reflected a group that were neither anxious nor depressed according to published cut-off scores (Bjelland, Dahl et al. 2002). The explanation as to why our study group was neither anxious nor depressed may lie in our patient selection criteria. Although functional outcome influences level of anxiety and depression, the extent of coexisting cognitive deficit and history of psychiatric illness also appear to play important roles in the presence and severity of

the depression observed in stroke (Perneger 1998). Our selection criteria (excluding presence or history of dementia) and baseline data supporting high cognitive function (mean MMSE 21.7) without psychiatric history (no cases) may have made the “grey” cohort even smaller in terms of capturing a depressed or anxious group within the larger population of patients with stroke. Excluding patients with dementia creating a biased sample has been suggested in other studies of quality of life outcome in stroke (Carod-Artal, Egido et al. 2000) although it could be argued that the alternative of including a more diverse group with less valid data isn’t a better option.

Failure to recover the ability to work has been identified as a major source of low quality of life for the stroke population (Carod-Artal, Egido et al. 2000). Although employment data was not collected for the SRO study, it might be presumed that return to work may be less of a cause for concern in this cohort where all patients were over 60 years of age. This may also have contributed to the low levels of depression and anxiety among the patients in the SRO study.

#### 8.2.3.2 Function

Results from unadjusted functional outcome measures suggested significant differences in both the BBS and the Chedoke McMaster posture inventory scores, but no other differences between facilities. After adjusting for covariates, there were no significant differences in any variable between facilities. Not surprisingly, BI, the baseline functional measure predicted most of the functional outcomes. In addition, age predicted FIM, BBS and Chedoke McMaster posture inventory scores. There are important factors to consider for each measure in interpreting these results.

Firstly, despite the fact that the FIM was the major functional outcome measure, it is important to consider that the SRO study was powered around the SF36 quality of life measure, and patient numbers limit the extent to which FIM data should be interpreted, as it turned out to be underpowered to detect significant differences

between facilities that may have been present and detectable in a larger sample. Unadjusted data suggested a magnitude of difference that although not statistically significant, approached the minimally important clinical difference before adjustment (Granger, Cotter et al. 1993). As the literature has demonstrated good construct validity between BI and FIM scores (Gosman-Hedstrom and Svensson 2000) and it is reasonable to assume that the baseline functional status would be associated with rehabilitation outcome, it is not surprising that the BI predicted FIM score in the adjusted model. The fact that FIM score was also predicted by age has been demonstrated previously in the literature (Bagg, Pombo et al. 2002). Considering the overall mean score, data suggests that patients remained somewhat dependant, and this reflects the sensitivity of the measure to detect disability.

The BBS evaluates both static and dynamic aspects of balance (see Chapter 4, *section 4.4.3*) and as discussed previously, unadjusted mean values at both time points demonstrated a statistically significant difference between facilities that was also clinically significant (more than 6) (Stevenson 2001). The SPC SU patients had better scores, although still below the threshold of 44, consistent with less risk of falling (Berg, Wood-Dauphinee et al. 1992). A Chedoke McMaster postural control inventory mean score of four fits with this picture, as it reflects lack of static righting and trunk segmentation required for higher balance function. After adjusting for covariates both variables showed no statistically significant differences, but scores remained below the safe threshold for falls. Both baseline BI and age predicted these scores, and as with the FIM, this was not surprising as the BI is another functional score that has been shown to correlate with the BBS (Berg, Wood-Dauphinee et al. 1992), and increasing age is associated with biomechanical changes that may affect balance and walking (Winter, Patla et al. 1990).

The literature suggests that the majority of stroke-survivors will walk again (Friedman 1990) and although gait speed has been shown to predict functional mobility and level of social activity (Jette, Keysor et al. 2005) there were no

statistically significant differences between groups in this study either before or after adjustment for covariates. It is interesting however that there was a change in the direction of the difference between facilities after adjustment, with SPC SU time becoming slower than those at GRUs.

It would have been useful to know the extent and timing of the provision of walking aids at both facility types because anecdotally, there is a perception that these aids are provided earlier in the GRUs compared to SPC SU in order to facilitate early discharge. The significantly shorter GRU length of stay supports this, although if walking aids were provided to this cohort, it did not follow that those patients were able to walk any faster than patients at SPC SU.

Several studies have suggested that gait speed is only one component of a complex package of measures defining “community ambulation”, such as the ability to walk on different terrains, and undertake other tasks concurrently (Jette, Keysor et al. 2005). The addition of a walking aid may have provided different scores in these domains highlighting differences between facility type that were not apparent with simple gait speed.

Overall gait speeds were slow compared to published healthy patient normative data (Bohannon 1997) and equivalent to speeds reported for household walkers post-stroke (Perry, Garrett et al. 1995) although the stroke cohort reported by Perry was slightly younger (minimum age 57 years), and there was no measure of their overall functional level in terms of ADL that could be compared with the present study sample. Perhaps it may simply be that a slow and steady walking pace was encouraged across all facilities rather than the faster gait speed of healthy individuals.

It has been suggested that 50% of stroke patients with initial upper limb impairment continue to have significant problems four years later (Broeks, Lankhorst et al.

1999). For the purposes of this study we used the total ARAT score to evaluate both sides of patients with cortical injuries thereby providing a holistic description of overall upper extremity function and therefore overall dependency, rather than only the hemiplegic side (Hsieh, Hsueh et al. 1998). Although no data is available that defines cut off scores (see Chapter 4, *section 4.4.1*), some papers propose that a 10% difference in total score represents a minimally important clinical difference (van der Lee, Beckerman et al. 2001; van der Lee, Leo et al. 2002). Differences between facilities (unadjusted difference of 1 and adjusted difference of 6) were therefore neither statistically nor clinically significant, and represented less than normal function in both groups.

Considering the relationship between poor upper limb function and shoulder pain (Feise 2002), it was not surprising that shoulder pain was evident in both groups at 6 and 12 months post-stroke. It follows that after adjusting for the facility type, overall function at baseline (as measured using BI score) predicted both ARAT and shoulder pain scores.

The incidence and severity of shoulder pain following stroke requires a management programme comprised of multiple components, including correct handling, positioning and education (Zeferino and Aycock 2010). Two specific components of SU care compared with care in the general ward (GW) are an organised team approach, and the education of a multidisciplinary team (Indredavik, Bakke et al. 1999). The demonstration of equivalent outcomes in this study suggests that staff in both the SPC SU and the GRUs provided good care for the upper limb. Another contributor to the similarity in outcome may be that all patients came from the same referring institution (RPH-WSC) and that practise relating to the care and protection of the upper limb at this facility is good and consistent there also.

With the overall non-significant differences across all of the adjusted functional measures, it is finally of interest to use the measures to define the functional level of



the “grey” cohort as a whole at follow-up. Overall the group remained somewhat dependent, with unadjusted mean FIM score 99.9, and at high risk of falling (Berg, Wood-Dauphinee et al. 1992), with Chedoke McMaster postural inventory score of 4 and BBS score less than 45. The Chedoke McMaster shoulder inventory score of 4 suggested that mild intermittent shoulder pain was experienced by the majority of patients.

#### 8.2.3.3 Treatment environment: behaviour mapping

Behaviour mapping was used to monitor and characterize the rehabilitation setting (see Chapter 7) as pilot data (see Chapter 3, *section 3.2.3*) had indicated that these data would provide useful information pertaining to the location and activity of patients within each facility, and detect differences if they existed.

Results revealed significant differences between facilities both in terms of where patients were located and how they spent their time. Whereas across all diagnoses, patients at the SPC SU were more likely than those in the GRUs to be in rehabilitation-specific areas such as the gymnasium, data pertaining specifically to the stroke patients suggested no differences in the amount of time spent in therapy areas between facilities. Patients at SPC SU were also less likely to be in the bed space and more likely to be active compared to GRU patients. The fact that differences were detected in the whole ward cohort suggests the rehabilitation ethos differs between facilities, whereby SPC SU patients were encouraged to be out of their rooms and attending rehabilitation, or at least be located in the rehabilitation area, observing other patients undergoing treatment. It also may be that the SPC SU model potentiates a culture of exercise and participation as patients were more active, even when they were alone.

Data also suggested that GRU patients spent more time interacting with visitors than those in the SU. This highlighted other differences in rehabilitation ethos, whereby visitors were able to access patients for longer periods throughout the day, but may

also be a reflection on the satellite nature of the GRUs that were generally located closer to the homes of resident inpatients. Overall, data reflected differences in rehabilitation attitudes between units, with emphasis placed on treatment (SPC SU) versus socialization with visitors (GRUs) regardless of the indication for admission (treatment of stroke or other pathology) or age within the cohort.

Importantly, age was significantly associated with bed space location, isolated and active behaviour whereby older patients with stroke were more likely to be in the bed space and isolated, and less likely to be involved in active behaviour.

#### 8.2.3.4 Cost: Length of stay and AHP diary information

Although the small numbers preclude rigorous statistical analysis, gross staffing levels as measured by FTE (see Chapter 7, Results and *Appendix 4*) reflect variation across facility type, with higher staffing at the SPC SU and this may in part explain the significant differences in the intensity of therapy applied there. This difference impacts on the total cost of rehabilitation services however, and although it may be expected that these costs would be offset by a shorter LOS at SPC SU, data suggests the opposite, with a significantly longer SPC SU LOS compared to the GRUs.

An explanation for this may be that the generally younger population at SPC SU might aim for higher functional recovery, whereby components of care such as the provision of walking aids (which may promote an earlier but more dependent discharge) are withheld (see Chapter 2, *section 2.4.5*) and LOS is prolonged. In the end, if functional outcome was no better in this group, our results demonstrated that shorter LOS with less intensive therapy is more cost efficient. It is important to remember that the conclusions may only be drawn for the “grey” group, and that in the overall scheme of the annual number of patients with stroke, this group is small (see Chapter 6, *section 6.2*).

Interestingly, the study comparing stroke rehabilitation models (Kalra, Evans et al. 2000) reported a median LOS of 22.5 days which was shorter than either SPC SU or the GRUs in the present study. This may reflect inherent differences in the level of national health funding for healthcare between Britain and Australia, or it may reflect a difference in practise in the ten years since the data was collected.

Results indicate that there were no differences in the number of different professions available to patients at each facility type, and that these included physiotherapy, occupational therapy, speech therapy and social work. This finding was in keeping with the overall SU ethos (whether at SPC SU or at any of the GRUs) of the availability of well trained multidisciplinary staff. Other professions (such as podiatry and clinical psychology) were also represented across both facility type, but not reported in view of the low frequency of their attendance during the study.

Data from the AHP diaries reflected that the intensity of therapy input in terms of total length of therapy time and indirect support (ward rounds and patient related meetings) were greater at the SPC SU. After adjustment for covariates, administration time (paper work and the recording of treatment statistics) was also found to be significantly higher at SPC SU. All of these factors were predicted by the baseline disability (BI score) of the patients, reflecting the fact that more disabled patients received most input.

Although these results fit with the anecdotal perceptions of the wider rehabilitation professional community and it is one of the factors believed to have inhibited recruitment into the RCT study design (see Chapter 5, *section 5.2.5*), they are different from those perceptions reported in pilot data whereby incumbent AHPs at each facility reported the same average length of stroke patient treatment sessions (see Chapter 3, *section 3.2.1.4*, *Figure 3.2.1.4f*).

These treatment intensity data were recorded in patient diaries that were pilot tested in the development of the study protocol (see Chapter 3, *section 3.2.2*). The manner in which data was recorded is important, as it took into account the environment in which the interaction took place. As stated previously (see 8.2.3.3), behaviour mapping of the units (see Chapter 7) demonstrated that overall, patients on the SPC SU were more likely to be in therapy areas like the gymnasium interacting in a group setting, and more likely to be active, whereas patients in the GRUs were more likely to be isolated in their bed space and inactive. At SPC SU mapping indicated that the therapist frequently had a number of patients simultaneously exercising, while he/she moved between patients providing individualised treatment. The therapist then divided their total time between as many patients as he/she was treating, only recording a fraction of time that the patient was actually undergoing supervised (though perhaps not “hands on”) treatment. In this way, although the cost of treatment in terms of AHP time was accurate and enabled efficient treatment, the extent of treatment intensity itself may have been underestimated at SPC SU. In contrast, diary data at the GRUs probably more accurately reflected both cost and treatment intensity, as treatments were more likely to be one-on-one.

There is little information in the literature about the amount of therapy received in different rehabilitation facilities. A landmark British randomised controlled trial published over 10 years ago was one of the first studies to attempt to quantify the amount of therapy received in different rehabilitation models (SU versus GW versus domiciliary care) for stroke patients (Kalra, Evans et al. 2000). The Kalra study cohort was similar in age and disability to that of the present study and their SU staff delivered a considerable amount of therapy. Almost all patients received physiotherapy (99%) and occupational therapy (99%) and the majority received speech therapy (70%). In terms of total treatment hours per patient, physiotherapists delivered the most (21.5), followed by occupational (6) and speech therapists (4). The present study has taken the evaluation of the SU model a step further by examining whether different models of SU provided different numbers of

professionals, variable duration of treatment and variable frequency of contact including hands on treatment, administrative care or indirect support. These data can also now be tied to the functional outcomes of each SU model that have been discussed previously in order that cost-effectiveness is examined.

Data relating to overall occasions of service split by profession reflect significant differences in occupational therapy, speech therapy and social work before adjusting for covariates, and in addition, significant differences in physiotherapy after adjustment. Data suggested that a higher number of SPC SU patients undergo speech therapy compared with GRU patients, and in addition, those that do have more intensive treatment.

Once again, all differences were predicted by disability (BI score), but it is of interest that when the longer SPC SU LOS was accounted for, the significance disappeared across all professions, except for speech therapy. This implies that patients from the “grey” group receive the same amount of input at each facility type, except for speech. This is not consistent with the general perception of neurological rehabilitation professionals within Western Australia that rehabilitation treatment is more intensive at SPC SU. That does not necessarily mean that the general perception is incorrect across the whole population of patients referred to SPC SU; but may just be that the lack of a difference for the subgroup of patients from the “grey” group is not perceptible when the population is considered anecdotally and as a whole.

#### 8.2.3.5 Discharge outcomes

Discharge destination data demonstrated no significant difference between facility type, with most patients discharged home. It may have been anticipated that the SPC SU patients would more likely be discharged home in the context of more intensive treatment over a longer hospital stay and a younger population. The large number of GRU patients who, perhaps given sufficient support, can also function at home was

not anticipated. This may correspond with the higher frequency of social work contact in the GRU group, enabling more home support services to be put in place for this cohort compared with the SPC SU. Overall, data is therefore suggestive of a “ceiling” effect for this “grey” cohort, whereby most patients are eventually discharged home.

#### 8.2.4 Bed blockage

Although RPH-WSC staff FTEs were not measured during the study, it is reasonable to assume that the resources available for rehabilitation in the acute setting were different from both the SPC SU and the GRUs. Bed blockage to either the SPC SU or the GRUs may have resulted in an acute rehabilitation intensity that did not reflect the rehabilitation facility patients were ultimately transferred to, and this could have influenced eventual functional outcome in either group. It is reassuring therefore that there were no significant differences between groups in either the time between stroke and referral, or the time between stroke and transfer to sub-acute rehabilitation despite there being relatively more GRU beds available, with three facilities compared to one SPC SU. The potential for bed blockage to influence outcome was equal in both groups and therefore not adjusted for in data analysis.

#### 8.2.5 Study endpoint at 12 months

Literature supports early rehabilitation in view of the rate of early functional improvement in stroke recovery (Aborderin 1996; Salter, Jutai et al. 2006). At the other end of the timeline, there are few studies of long term rehabilitation, such that both the outcomes and cost-effectiveness of such treatments are inconclusive (Aziz NA, Leonardi-Bee J et al. 2008). In the current study, no follow-up data were collected after 12 months post-stroke. We are therefore limited in the extent to which conclusions can be drawn relating to differences in the long term functional outcome of patients at each facility type. These data may detect differences and in any case would provide more information about the “grey” cohort if collected in the

future, however in the current study, the changes between 6 and 12 months were very small for most variables, and not significant.

### 8.3 Limitations

#### 8.3.1 Outcome measures for speech therapy

Although a wide range of appropriate outcome measures were chosen to detect differences between facility type, there was no speech therapy-specific outcome. Baseline data reflected a significantly different incidence of abnormal language of stroke patients in the SPC SU cohort compared to the GRUs, and correspondingly, rehabilitation measures suggested differences in the amount of speech therapy intervention undertaken at SPC SU. These data support the premise that patients requiring speech therapy may be directed to SPC SU based on better speech therapy outcome, but we did not measure this to support or refute the assumption.

#### 8.3.2 Ongoing cost associated with discharge home

An interesting outcome of the study was that no significant differences were found in the discharge destination between groups, with most patients being discharged home. A limitation of the study is the fact that the extent of this domiciliary assistance (such as the showering and dressing assistance and meal preparation) was not measured to enable more detailed cost-comparison between facility type.

#### 8.3.3 Therapist bias and compliance

All incumbent therapy staff agreed to participate in the collection of data for the SRO trial, and all therapists were aware of which of their patients were enrolled in the study. This was required for ethical approval, but also in order to have staff complete patient diary information. The fact that staff were not blind to the SRO cohort may have meant that they treated study patients differently than usual

(perhaps more often or for longer). There was no way to control for this, but the potential for the bias was the same in both groups.

In addition, although patients were asked to remind attending staff, their compliance in completing diary data, although monitored periodically with informal telephone calls, was not measured. It may be for example that the social workers at SPC SU, who are underrepresented in occasions of service, did not comply with the recording of diary data related to their care.

#### 8.3.4 Patient recruitment

Pilot data collected during 2001 (see Chapter 3, *section 3.1.2*; Chapter 5, *sections 5.2.2.4 and 5.3.2.4*) suggested that there would be enough appropriately aged patients with stroke presenting to RPH-WSC to allow recruitment of sufficient numbers for the SRO study within 18 months. Results reflect a slower rate of recruitment, within a period of 30 months. This may be explained by both patient characteristics and the practical considerations.

Patient characteristics that may in part explain slow recruitment included the number of patients having to be excluded from the cohort due to the presence or history of dementia or confusion, which although not an uncommon characteristic of stroke, was not anticipated. There were also patients exhibiting dysphasia (either receptive or expressive) that precluded informed written consent and thereby recruitment. In addition, a number of patients refused to be involved in the study. Reasons provided included the perception that the research would add burden to the stress of the acute illness; that they did not wish to be followed up for assessments not considered a specific component of their treatment; and that they did not want to add to their partner or carer's burden by having them have to transport them to additional outpatient appointments following hospital discharge.



From a practical standpoint, although the incumbent referral system (described in Chapter 5, *section 5.3.2.2*) accommodated our study, there were patients who were “missed” for screening and consent. These “missed” patients were usually transferred earlier than anticipated when a bed became available at one type of facility or other. In addition, although the number of patients presenting during the period had increased since pilot data was first collected (see Chapter 6, *section 6.2*) there were still a large number of patients that were discharged to facilities other than those involved in the SRO study (see Chapter 6, Figure 6.2c) and these patients were excluded from the study.

After all of these considerations it may also simply have been that there were just not as many patients in the “grey” area as had been anticipated, and capturing those that were for the purposes of a research study took longer based on these numbers. Importantly, after 30 months and considering the number of patients discharged home rather than attending inpatient rehabilitation, actual numbers recruited were sufficient for powering the primary outcome measure.

### 8.3.5 Study timeline

The timeline for this study was extended over four periods, with initial delay due to difficulties with recruitment into the RCT study design, subsequent delay during the changeover to a new observational study design, and delay with slower than expected rate of patient recruitment into this model,. These extensions have culminated in the drawing of conclusions from data collected almost 8 years ago. During this period, there has been no change in patient admission criteria to the rehabilitation units concerned (SPC SU and GRUs), the number of rehabilitation beds available or gross staffing levels, such that conclusions drawn from past data should remain as relevant and applicable to the 2012 cohort of RPH-WSC patients with stroke as they were 8 years ago.



## CHAPTER 9

### Conclusion

While there is no doubt that the literature supports the treatment of stroke patients in dedicated stroke units rather than general wards, questions remain regarding whether the overall organisation and operation of the stroke units situated in neurological wards versus those existing within geriatric facilities are different. The impact of these differences on the different subgroups of the stroke patient population are also therefore unknown, but may in themselves potentiate different functional outcomes in certain groups.

Whatever the organisation and operation, it is generally accepted that young patients with the capacity for intensive treatment and the requirement for extensive rehabilitation in order to return to work should receive rehabilitation at neurological stroke units. At the other end of the spectrum, older patients with less potential for intensive treatment but a more urgent requirement for early return to a familiar home environment should be transferred for treatment in geriatric stroke units. The intermediate “grey” group of stroke-survivors comprising those patients falling somewhere in between the other more discrete groups have been the focus of this study. These patients were over 60 years of age and had the capacity to undertake reasonably intensive rehabilitation in view of a limited number of comorbidities and good social support, such that the decision to recommend one type of unit over another was arbitrary in that the referring physician had no evidence to support superior outcome at either facility.

Pilot data suggested that the GRU population as a whole comprised a more varied group in terms of diagnosis, age, dependency, and cognitive function compared to the SPC SU pool. Patients at either end of the rehabilitation spectrum (young and able or older and with cognitive deficit) who were not the subject of this study none

the less helped define the environment in which the “grey” cohort undertook their rehabilitation. Behaviour mapping data quantified the differences that had been perceived anecdotally in pilot surveys of incumbent staff, by describing where patients were and what they were doing during the day at the different facilities. Patients undergoing rehabilitation at the GRUs were less likely to be located in therapy and less likely to be actively engaged in rehabilitation than SU patients. They were also more likely to be located in the bed space and to be isolated rather than engaged.

Diary data quantified whether these environmental differences impacted on the likelihood of equivalent care in terms of the professionals delivering care and the frequency and length of treatment at each facility. Although unadjusted diary data demonstrated differences in terms of treatment intensity, when adjustments were made for covariates, results reflect that both groups received similar treatment, albeit in significantly different surroundings as defined by the overall rehabilitation population and the physical environment.

Moreover, actual (unadjusted) measures demonstrate that despite a longer LOS with more intensive, costly therapy in locations specific to therapy at SPC SU, quality of life and functional outcomes were not significantly different from the outcomes of patients on GRUs. Consideration should also be taken of the fact that the study was underpowered to detect differences with the primary functional outcome (the FIM).

Although the statement cannot be generalised to all patients with stroke, it would appear that this “grey” cohort do equally as well at either type of stroke unit, as there is no evidence to support the superiority of one over another in this specific cohort.

It follows that the recommendations for future referral of the “grey” patient cohort may be that

- from a cost/outcome perspective, in most cases, they should preferably be transferred to GRUs rather than the SPC SU
- higher patient/ staff ratios, and less intensive treatments with shorter LOS may not be associated with poorer outcome at GRUs
- there may be exceptions in particular patients requiring speech therapy, who may be more suited to SPC SU than the GRUs despite increased cost and the same functional outcomes in other measures

Future functional outcome studies powered around the FIM are needed to investigate possible differences that were not detected in the present study. Further, studies evaluating differences in speech therapy outcomes in this population are also needed in this cohort.



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## APPENDIX 1

Pilot allied health professional questionnaire

### QUESTIONNAIRE TO CLINICIANS IN FACILITIES DEALING IN STROKE PATIENTS TRANSFERRED FROM ROYAL PERTH HOSPITAL

Please identify the facility in which you currently work:

☐ Royal Perth Hospital, Shenton Park Campus

☐ Swan Districts Hospital

☐ Mercy Hospital

☐ Bentley Hospital

In what year did you graduate and with what qualification

19\_\_\_\_\_ 200\_\_\_\_\_

Have you enrolled in post-graduate studies?

Yes                      No

Please give details of post-graduate qualifications (if any)

Please give details of your achievements if a qualification was not completed)

During your career, how many years/months have you been involved in the treatment  
of stroke patients?

How often do you attend continuing education dealing with the treatment of  
neurological conditions?

weekly                      monthly                      six monthly                      annually                      other\_\_\_\_\_

Give examples of the length and focus of all continuing education you have attended in the last 2 years

Indicate which area of care you are primarily involved with:

Rehabilitation ward (inpatient)

Day Hospital (outpatient)

On average how many patients are you responsible for the provision of therapy daily within your facility

Of these, how many of these patients would have stroke as their primary diagnosis?

Estimate the total time (minutes) you allocate to the assessment, treatment and documentation of all patients with stroke on an average day

Estimate your average treatment time (minutes) with a stroke patient with stroke on an average day

Mark on the continuum where you consider the underlying philosophy of your approach to treating patients with acute or subacute stroke to be

-----

Compensatory

Facilitatory

Mark on the continuum where you consider your perception of the care you are able to provide to patients with stroke under your care

-----

Less than optimal

average

optimal

-----

optimal

If you treat inpatients, how much input do you have in the overall patient length of stay at your facility?

Maximal

5



## APPENDIX 2

Final allied health professional questionnaire

### QUESTIONNAIRE TO CLINICIANS IN FACILITIES DEALING IN STROKE PATIENTS TRANSFERRED FROM ROYAL PERTH HOSPITAL

Please give your FTE working equivalency:

Fulltime      Partime FTE

Please identify the facility in which you currently work:

☐ Royal Perth Hospital, Shenton Park Campus

☐ Swan Districts Hospital

☐ Mercy Hospital

☐ Bentley Hospital

In what year did you graduate and with what qualification

19\_\_\_\_\_ 200\_\_\_\_\_

Have you enrolled in post-graduate studies at a recognised tertiary institution?

Yes

No

If yes, which institution?

Please give details of post-graduate qualifications completed at this tertiary institution

Please give details of your achievements if a qualification was not completed at this tertiary institution (for example, the number of units completed)

Please give details/ study title of any research in the area of neurological rehabilitation that you have been directly involved with

During your career, how many years/months have you been involved in the treatment of patients with stroke

How often do you attend continuing education dealing with the treatment of neurological conditions \_\_\_\_\_ weekly  
monthly      six monthly      annually      other\_\_\_\_\_

Please give examples of the length and focus of all continuing education dealing with the assessment and treatment of neurological conditions you have attended in the last 2 years

Indicate which area of care you are primarily involved with:

Rehabilitation ward (inpatient)      Day Hospital (outpatient)

On average how many patients are you responsible for the provision of therapy daily within your facility

Of these, how many of these patients would have stroke as their primary diagnosis

Estimate the total time (minutes) you allocate to the assessment, treatment and documentation of all patients with stroke on an average day



Estimate your average assessment, treatment and documentation time (minutes) spent with a single patient with stroke on an average day

Please estimate in percentage the distribution of your assessment and treatment that is based on each of the following approaches

|                   |         |
|-------------------|---------|
| ⑥Bobath           | _____ % |
| ⑥PNF              | _____ % |
| ⑥Rood             | _____ % |
| ⑥Motor Relearning | _____ % |
| ⑥Brunstrom        | _____ % |
| ⑥Other            | _____ % |
|                   | 100 %   |

Mark on the continuum where you consider the underlying philosophy of your approach to treating patients with acute or subacute stroke to be

-----

|              |              |
|--------------|--------------|
| Compensatory | Facilitatory |
|--------------|--------------|

Mark on the continuum where you consider your perception of the care you are able to provide to patients with stroke under your care

-----

|                   |         |         |
|-------------------|---------|---------|
| Less than optimal | average | optimal |
|-------------------|---------|---------|

If less than optimal, please describe why

---

optimal

Minimal

Maximal

3

## APPENDIX 3

Patient consent form for diary pilot study

MAIN STUDY TITLE: Outcomes of different rehabilitation approaches in patients post-stroke: a randomised controlled trial

PILOT STUDY: Completion of Treatment Diaries

PATIENT CONSENT FORM

Having read the Stroke Rehabilitation Diary, I,

\_\_\_\_\_ hereby consent to participate in the pilot study described, enabling investigators to obtain a better idea about the amount and type of rehabilitation services offered to patients with Stroke at this hospital facility. I therefore also agree to carry the diary with me for 5 days, and, where possible, have all appropriate staff complete treatment details.

I have been given the opportunity to ask questions about the study, and I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the trial.

Signed ..... Date .....

Signature of Investigator ..... Date .....

INVESTIGATORS: DIANE DENNIS, KATHY BRIFFA, GRAEME HANKEY  
LEON FLICKER



## APPENDIX 4

Final patient diary template

### STROKE REHABILITATION DIARY

The purpose of this Diary

The data required in this diary is an important part of information needed to complete a Stroke Rehabilitation study being performed at this hospital and other rehabilitation facilities in Perth. The purpose of the study is to obtain a clear picture of the rehabilitation costs and patient outcomes at the different facilities.

What information is required

It is important that we receive accurate information regarding the amount and type of rehabilitation services offered to each stroke patient enrolled in this study. This includes the name of the professionals who work with this patient, their profession (eg. Physiotherapist, Occupational Therapist, Speech Pathologist, Social Worker, etc), their level of employment and how long they spend with each patient.

How to complete each page

Please complete details of your intervention on the following pages that have been colour coded according to profession:

|                         |          |
|-------------------------|----------|
| Physiotherapists        | (green)  |
| Occupational Therapists | (blue)   |
| Speech Pathologists     | (pink)   |
| Social Workers          | (purple) |
| Other groups            | (yellow) |

Fill in the date, your initials and the time you spend each day with this patient. Definitions of Therapy Time, General Administration Time and Round Administrative Time can be found on the last page of this diary. Also specify the location of treatment in the location column. Please indicate in the white pages any

significant events (if there should be any) relevant to the patient's daily routine care. These events could be positive or negative and could include things such as falls, new illnesses other than those already documented (eg colds, shingles, chest pain), outpatient appointments, home visits, day leave or birthdays.

Please Don't Forget to Complete the Last Page

On the last page, please complete your profession, your printed name, your initials and your level of appointment (for example Student, Aide, Level 3/5, Level 6).

Diary for: (PATIENT STICKER)

| DATE                | INITIALS | THERAPY<br>Time<br>(in minutes) spent<br>with patient over<br>the number of<br>patients<br>concurrently in<br>therapy area | GENERAL<br>ADMIN Time (in<br>minutes)<br>spent on<br>patient notes,<br>general paper<br>work, or statistics | ROUND ADMIN<br>Time (in minutes)<br>spent discussing<br>patient on ward<br>rounds/ meetings as<br>fraction of total<br>time of meeting | LOCATION<br><br>Bedside (B)<br><br>Therapy Gym/Rm<br>(T)<br><br>Office (O)<br><br>Other (X) |
|---------------------|----------|--|---|--|---|
| Eg.<br>04/0<br>6/04 | DD       | 45/3 (45 minutes<br>spent with this pt<br>whilst 2 others pts<br>in gym too)   |   |  | G   |

### Definitions

Therapy Time refers to time spent with the patient and /or family in rehabilitation. It should include family meetings and telephone conversations related to the patient.

If there are other patients in the treatment area during your therapy session with this patient, please record only the individual time you spend with this patient (not the entire time of the therapy session). Put that number over the number of people in the therapy area. For example, if 3 patients were being treated concurrently in a gym setting for a total of 50 minutes, and the stroke study patient received 25 minutes of

the therapist's individual attention, it would be recorded as 25/3. If there were no other patients present in the gym, and this patient received 25 minutes of therapy, it would be recorded as 25/1. If more than 1 therapist treats the same patient at the same time, they should each individually record their times.

General Administration Time refers to time spent writing notes, letters, or completing statistics pertaining to the patient.

Round Administrative Time refers to time spent attending general ward rounds or meetings pertaining to the patient. On a ward round, if the total meeting time was 60 minutes and this patient was discussed for 10 of those minutes, each therapist should individually record a time of 10/60.

Thank you for taking the time to provide us with this valuable information. If you have any questions regarding this trial or the completion of this diary, please feel free to contact the study coordinator:

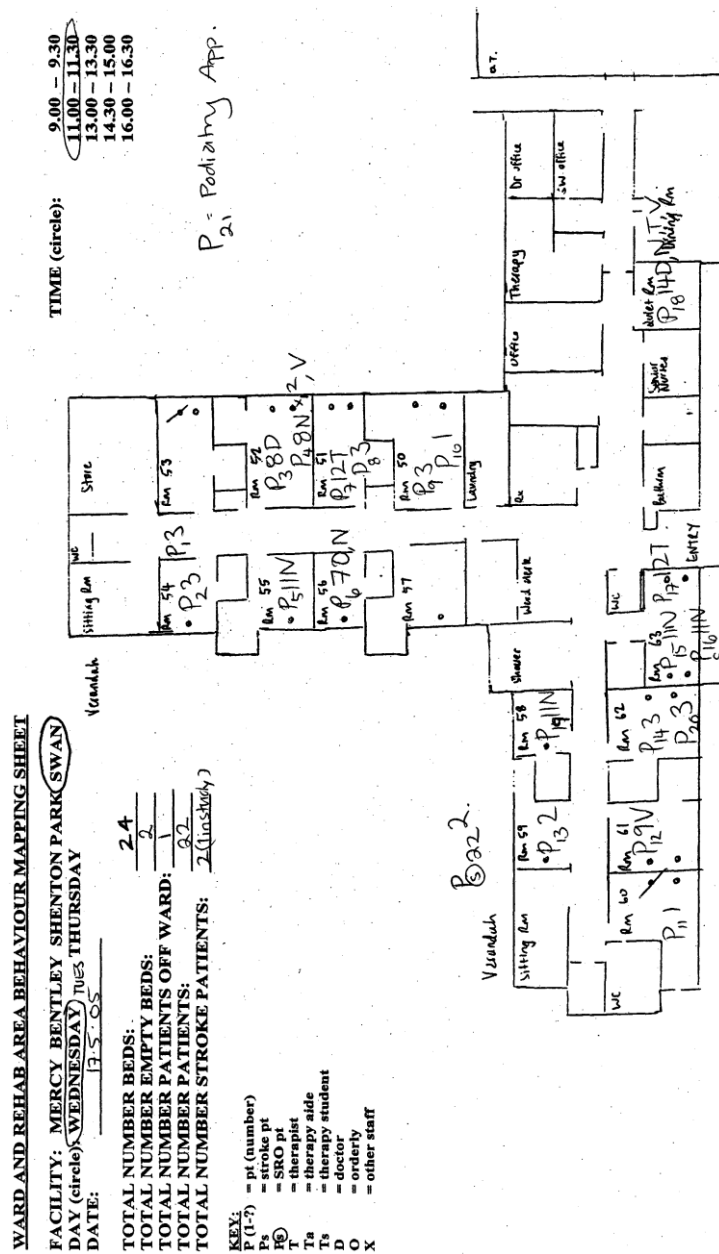
#### Record of Professionals Working With This Patient

| Profession | Printed Name | Initials | Level of Appt. (eg. Level 6) |
|------------|--------------|----------|------------------------------|
|            |              |          |                              |
|            |              |          |                              |
|            |              |          |                              |





### Example of completed war behaviour map

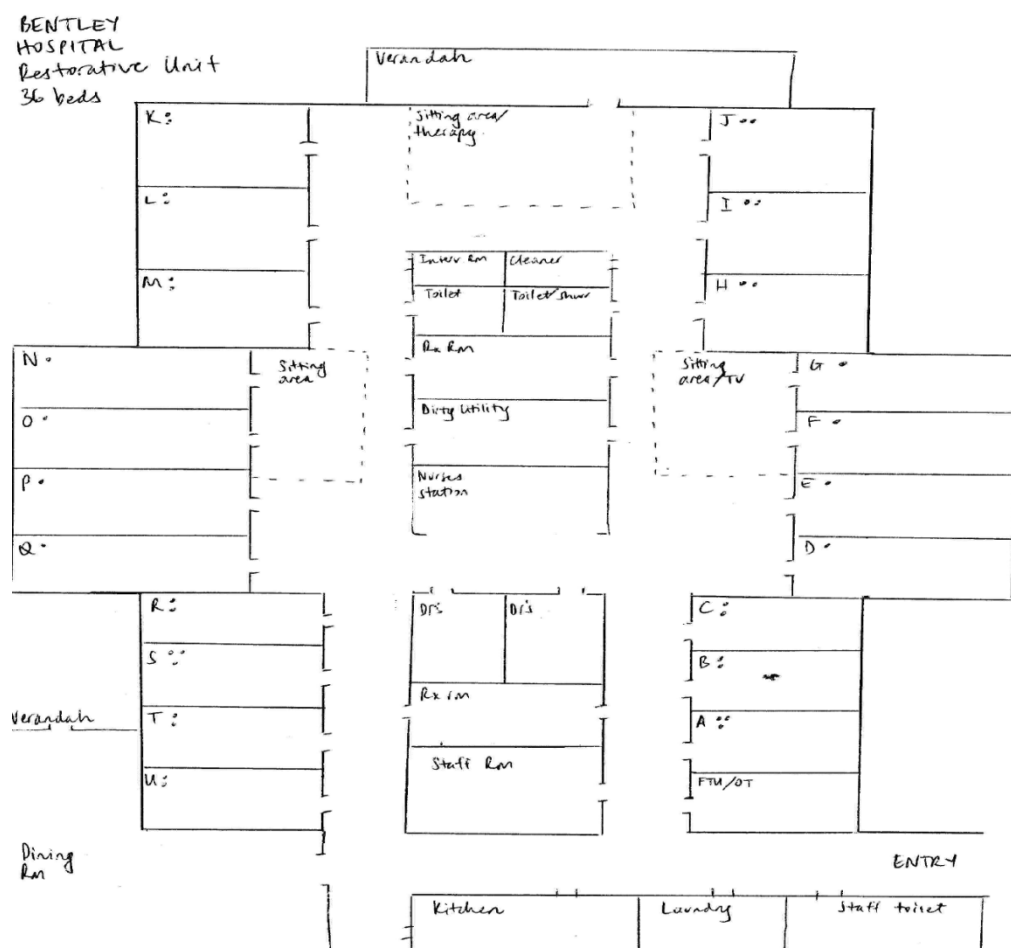




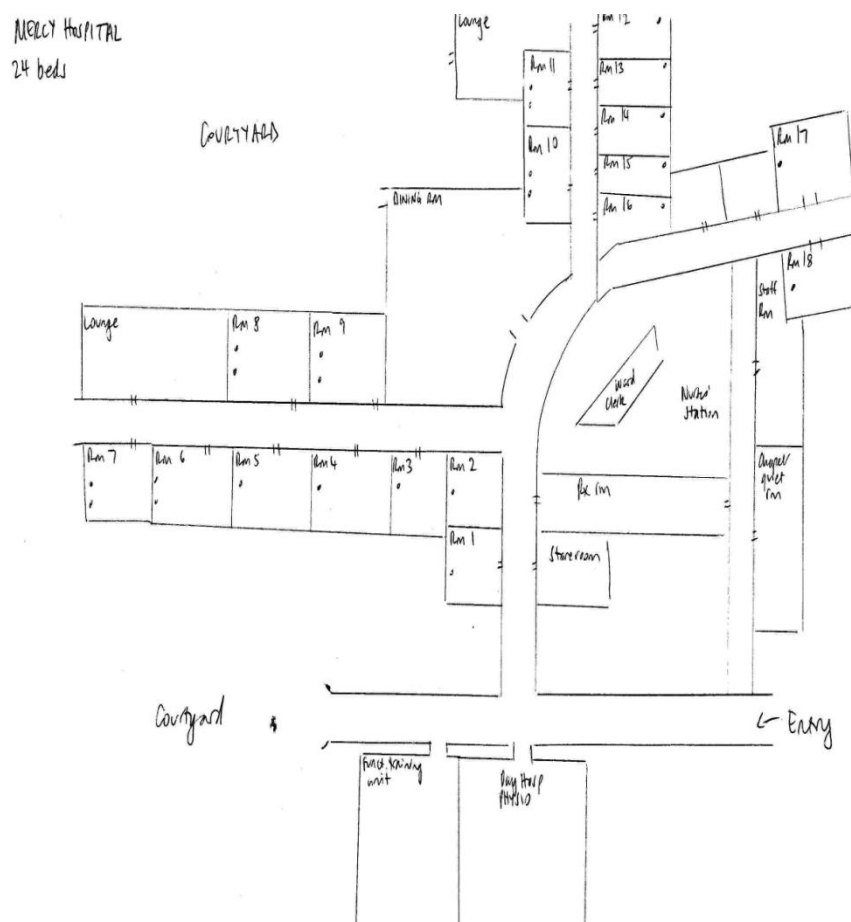
## APPENDIX 6

### Maps

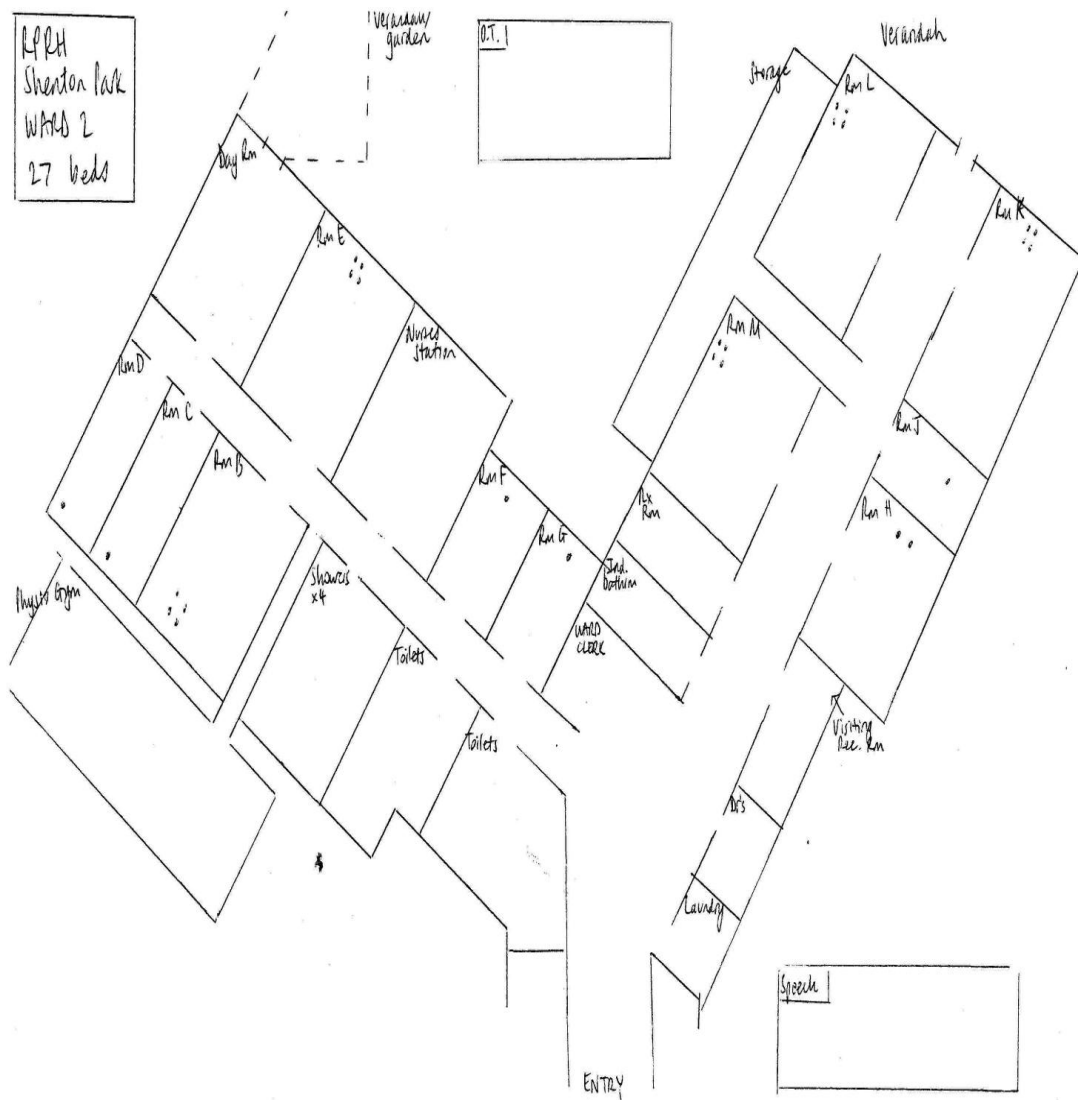
#### Topographical map – Bentley GRU



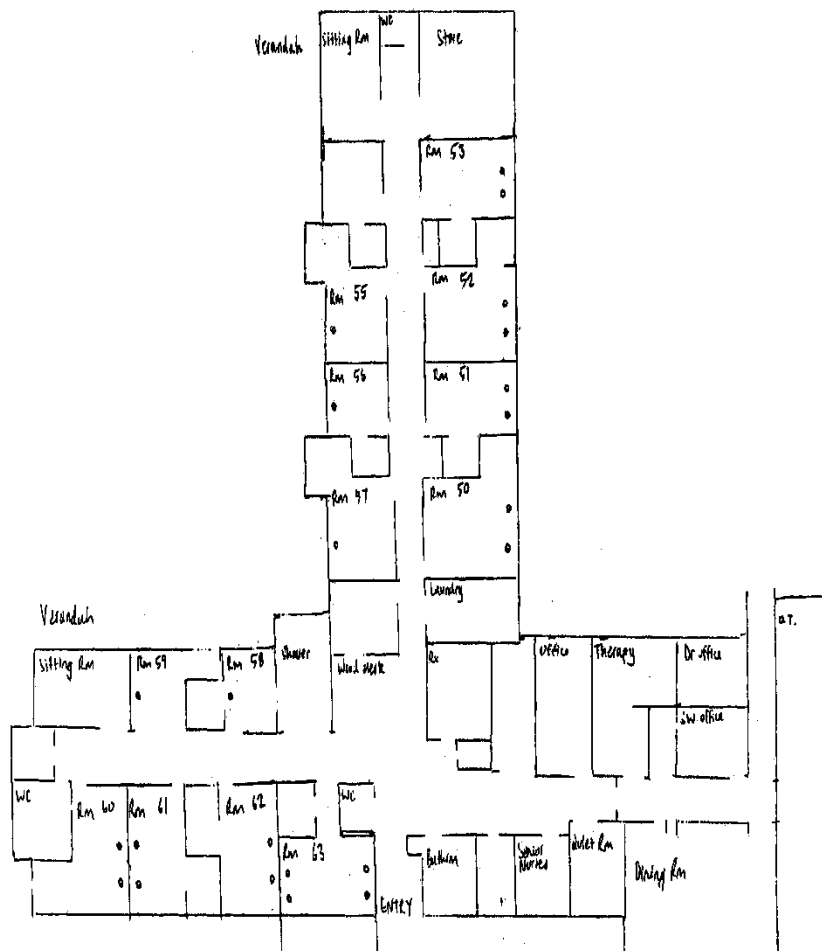
## Topographical map - Mercy GRU



# Topographical map SPC SU



## Topographical map – Swan Health Service GRU



## APPENDIX 7

Pilot patient-based mapping template

PATIENT    A            B            C            DAY            1            2            3

CATEGORY (1-!0) \_\_\_\_\_

THERAPY

DISCIPLINE:

LOCATION:

PATIENT POSITION:

AHP POSITION:

OTHERS PRESENT:            Y            N

Detail (number pts, staff ; active/ inactive)

Receiving treatment concurrently?

THERAPY DESCRIPTION

TASK ORIENTATED:            Y            N

Detail

AHP'S

HANDS                            ON      OFF

VERBAL COMMANDS    Proprioceptive                            Biomechanical

Task Related                            Other

Frequent                            Infrequent

#### OVERALL TREATMENT APPROACH

|  |   |   |                |
|--|---|---|----------------|
| BODY PART TREATED EXPOSED                          | Y | N |                |
| DAILY TREATMENT REPEATED                           |   | Y | N (days 2 & 3) |
| INDEP PRACTISE ENCOURAGED                          | Y | N |                |
| OTHER (Self propelling, walking with n/staff, etc) |   |   |                |



## **APPENDIX 8**

Pilot patient-based behaviour mapping patient information sheet

MAIN STUDY TITLE: Outcomes of different rehabilitation approaches in patients post-stroke: a randomised controlled trial

PILOT STUDY: Completion of Behaviour Mapping

### **PATIENT INFORMATION SHEET**

#### **Introduction**

Stroke is a common illness in most western countries requiring rehabilitation. This rehabilitation is complicated and may involve many professionals. The best recovery of daily function is the ultimate goal, and it is important that patients are provided with every opportunity to achieve their greatest potential.

There are many different approaches to rehabilitation and little scientific evidence to favor one approach over another. Many studies have noted that although patients having suffered similar types of strokes originally, their functional outcome is quite variable. In Perth, there are a number of different types of facilities that offer stroke rehabilitation. We are presently unsure of the suitability of one facility type over another for some patients. The purpose of the main study will be to see whether the level of recovery differs between rehabilitation facilities.

You have been asked to participate in this PILOT study because you have had a stroke requiring further rehabilitation.

What does the PILOT STUDY involve?

If you agree to participate in the pilot study, your activity will be observed for approximately 15 minutes every hour between 8.30am and 5.00 pm over 3 consecutive days. During this time the observer will record details of your activity.

### Benefits and Risks

There are no benefits or risks for you in the trial, as you will receive rehabilitation whether or not you participate in the study. You will however be providing valuable information for doctors and therapists of future stroke patients by participating.

### Withdrawal from the study

Your participation in the study is entirely voluntary. You may withdraw from the study at any time without explanation and without it affecting your treatment.

If you have any questions at any time during the Behaviour Mapping, you are welcome to telephone the study coordinator Diane Dennis on 93716319

## APPENDIX 9

Pilot patient-based behaviour mapping patient consent form

MAIN STUDY TITLE: Outcomes of different rehabilitation approaches in patients post-stroke: a randomised controlled trial

PILOT STUDY: Completion of Behaviour Mapping PATIENT CONSENT

Having read the Patient Information Sheet, I, \_\_\_\_\_  
hereby consent to participate in the pilot study described, enabling investigators to obtain a better idea about the amount and type of rehabilitation services offered to patients with Stroke at this hospital facility.

I have been given the opportunity to ask questions about the study, and I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the trial.

Signed..... Date.....

Signature of Investigator ..... Date.....

INVESTIGATORS:

DIANE DENNIS

KATHY BRIFFA

GRAEME HANKEY

LEON FLICKER



## **APPENDIX 10**

Pilot patient-based behaviour mapping patient therapist information sheet

MAIN STUDY TITLE: Outcomes of different rehabilitation approaches in patients post-stroke: a randomised controlled trial

PILOT STUDY: Completion of Behaviour Mapping.

### **THERAPIST INFORMATION SHEET**

#### **Introduction**

Stroke is a common illness in most western countries requiring rehabilitation. This rehabilitation is complicated and may involve many professionals. The best recovery of daily function is the ultimate goal, and it is important that patients are provided with every opportunity to achieve their greatest potential.

There are many different approaches to rehabilitation and little scientific evidence to favor one approach over another. Many studies have noted that although patients having suffered similar types of strokes originally, their functional outcome is quite variable. In Perth, there are a number of different types of facilities that offer stroke rehabilitation. We are presently unsure of the suitability of one facility type over another for some patients. The purpose of the main study will be to see whether the level of recovery differs between rehabilitation facilities.

You have been asked to participate in this PILOT study because you are involved in the treatment of patients with stroke requiring further rehabilitation.

What does the PILOT STUDY involve?

Activity on the restorative ward will be observed between the hours of 8.30am and 5.00pm over 3 consecutive days (Tuesday 27th April to Thursday 29th April, inclusive). Two methods of observation will be used: Firstly, three patients will each

be followed for 15 minutes of every hour, and their activity will be recorded. Secondly, an observer will perform a walk-through the ward (during the remaining 15 minutes of each hour) to observe all patient's activity. Nursing, Allied Health and Axillary staff's presence will be recorded in the second method, but not their activity.

#### Benefits and Risks

There are no benefits or risks for you in the trial, and patients will receive rehabilitation whether or not you participate in the study.

#### Withdrawal from the study

Your participation in the study is entirely voluntary. You may withdraw from the study at any time without explanation.

#### Ethics and Consent

Mercy Ethics committee and all of the Medical Consultants involved on the Restorative Ward have consented to the involvement of their patients in the study. In addition, the three patients who will be followed during the period will be individually consented.

If you have any questions at any time during the Behaviour Mapping, you are welcome to telephone the study coordinator Diane Dennis on 93716319

## APPENDIX 11

Generic daily routine template

Facility (CIRCLE): MERCY      BENTLEY      SHENTON PARK      SWAN

Date: \_\_\_\_\_

Preparation:

8.30 – 9.00

Check total number patients on the ward

Identify patients with stroke versus other diagnosis

Document known appointments during the day

Document therapy programs where appropriate

Collate individual patient maps and sheets according to how many SRO patients are at the facility (max 4 – patients A,B,C,D)

Will need 5 ward and rehab area maps per day and up to 16 individual maps per day

Mapping Programme:

9.00 – 9.30    Ward and Rehab Area Behaviour Map 1

9.30 – 10.30    Individual (15 minute) Behaviour Maps (up to 4 patients) 1

9.30 – 9.45    Patient A      \_\_\_\_\_

9.45 – 10.00    Patient B      \_\_\_\_\_

10.00 – 10.15    Patient C      \_\_\_\_\_

10.15 – 10.30    Patient D      \_\_\_\_\_

10.30 – 11.00    Begin to collate Data

11.00 – 11.30    Ward and Rehab Area Behaviour Map 2

11.30 – 12.30    Individual (15 minute) Behaviour Maps (up to 4 patients) 2

11.30 – 11.45    Patient D      \_\_\_\_\_

11.45 – 12.00    Patient A      \_\_\_\_\_

12.00 – 12.15    Patient B      \_\_\_\_\_

Generic topographical demographic template 12.15 – 12.30 Patient C

---

12.30 – 13.00 LUNCHBREAK

13.00 – 13.30 Ward and Rehab Area Behaviour Map 3

13.30 – 14.30 Individual (15 minute) Behaviour Maps (up to 4 patients) 3

14.30 – 14.45 Patient C \_\_\_\_\_

14.45 – 15.00 Patient D \_\_\_\_\_

15.00 – 15.15 Patient A \_\_\_\_\_

15.15 – 15.30 Patient B \_\_\_\_\_

14.30 – 15.00 Ward and Rehab Area Behaviour Map 4

15.00 – 16.00 Individual (15 minute) Behaviour Maps (up to 4 patients) 4

15.00 – 15.15 Patient B \_\_\_\_\_

15.15 – 15.30 Patient C \_\_\_\_\_

15.30 – 15.45 Patient D \_\_\_\_\_

15.45 – 16.00 Patient A \_\_\_\_\_

16.00 – 16.30 Ward and Rehab Area Behaviour Map 5



# WARD AND REHAB AREA BEHAVIOUR MAPPING SHEET

FACILITY: MERCY BENTLEY SHENTON PARK SWAN

TIME (circle):

9.00 – 9.30

DAY (circle): WEDNESDAY THURSDAY

11.00 – 11.30

DATE: \_\_\_\_\_

13.00 – 13.30

14.30 – 15.00

16.00 – 16.30

TOTAL NUMBER BEDS: \_\_\_\_\_

TOTAL NUMBER EMPTY BEDS: \_\_\_\_\_

TOTAL NUMBER PATIENTS OFF WARD: \_\_\_\_\_

TOTAL NUMBER PATIENTS: \_\_\_\_\_

TOTAL NUMBER STROKE PATIENTS: \_\_\_\_\_

KEY:

P (1-?) = pt (number)

Ps = stroke pt

Ps = SRO pt

T = AHP

Ta = therapy aide

Ts = therapy student

D = doctor

O = orderly

X = other staff



## APPENDIX 12

Final patient-based mapping template

FACILITY (circle): MERCY BENTLEY SHENTON PARK SWAN

DAY (circle): WEDNESDAY THURSDAY

DATE: \_\_\_\_\_

PATIENT (circle): 1 2 3 4

TIME (circle):

LOCATION (circle):

|   |  |
|---|--|
| 1 | 9.30 – 9.45<br>9.45 – 10.00<br>10.00 – 10.15<br>10.15 – 10.30    |
| 2 | 11.30 – 11.45<br>11.45 – 12.00<br>12.00 – 12.15<br>12.15 – 12.30 |
| 3 | 13.30 – 13.45<br>13.45 – 14.00<br>14.00 – 14.15<br>14.15 – 14.30 |
| 4 | 15.00 – 15.15<br>15.15 – 15.30<br>15.30 – 15.45<br>15.45 – 16.00 |

|   |                     |
|---|---------------------|
| B | Bedspace            |
| S | Shower /Toilet      |
| G | Gymnasium           |
| T | Other therapy area  |
| H | Hallway             |
| D | Dining Room         |
| S | Sitting/ Day Room   |
| O | Off ward or outside |

| CATEGORY<br>(1 –15) | DESCRIPTION<br>(when indicated) | LOCATION<br>(code) | TIME in minutes<br>(should total 15) |
|---------------------|---------------------------------|--------------------|--------------------------------------|
|                     |                                 |                    |                                      |
|                     |                                 |                    |                                      |
|                     |                                 |                    |                                      |
|                     |                                 |                    |                                      |
|                     |                                 |                    |                                      |
|                     |                                 |                    |                                      |

## APPENDIX 13

### Action Research Arm Test (ARAT)

#### Action Research Arm Test

##### Scoring:

- 3: Performs the test normally
- 2: Completes test but takes abnormally long time
- 1: Performs test partially
- 0: Can perform no part of test

- If the subject passes the first, no more need to be administered and he scores top marks for that subtest;
- If the subject fails the first and fails the second, he scores zero, and again no more tests need to be performed in the subtest;
- Otherwise he needs to complete all of the tasks in the subtest

|                                       |   | Side         |               |
|---------------------------------------|---|--------------|---------------|
|                                       |   | Left         | Right         |
| <i>Grasp</i>                          |   |              |               |
| 1                                     | Block, wood, 10-cm cube (If score = 3, total = 18 and go to <i>Grip</i> ) | _____        | _____         |
|                                       | Pick up a 10-cm block   | _____        | _____         |
| 2                                     | Block, wood, 2.5-cm cube (If score = 0, total = 0 and go to <i>Grip</i> ) | _____        | _____         |
|                                       | Pick up 2.5-cm block  | _____        | _____         |
| 3                                     | Block, wood, 5-cm cube  | _____        | _____         |
| 4                                     | Block, wood, 7.5-cm cube  | _____        | _____         |
| 5                                     | Ball (Cricket), 7.5-cm diameter   | _____        | _____         |
| 6                                     | Stone 10 x 2.5 x 1 cm   | _____        | _____         |
| Coefficient of reproducibility = 0.98 |   |              |               |
| Coefficient of scalability = 0.94     |   |              |               |
| <b>Total</b>                          |   | Left = _____ | Right = _____ |
| <i>Grip</i>                           |   |              |               |
| 1                                     | Pour water from glass to glass.   | _____        | _____         |
|                                       | (If score = 3, total = 12 and go to <i>Pinch</i> )                        | _____        | _____         |
| 2                                     | Tube 2.25 cm  | _____        | _____         |
|                                       | (If score = 0, total = 0 and go to <i>Pinch</i> )                         | _____        | _____         |
| 3                                     | Tube 1 cm x 16 cm   | _____        | _____         |
| 4                                     | Washer (3.5 cm diameter) over bolt  | _____        | _____         |
| Coefficient of reproducibility = 0.99 |   |              |               |
| Coefficient of scalability = 0.94     |   |              |               |
| <b>Total</b>                          |   | Left = _____ | Right = _____ |
| <i>Pinch</i>                          |   |              |               |
| 1                                     | Ball bearing, 6 mm, 3rd finger and thumb                                  | _____        | _____         |
|                                       | (If score = 3, total = 18 and go to <i>Grossmt</i> )                      | _____        | _____         |
| 2                                     | Marble, 1.5 cm, index finger and thumb                                    | _____        | _____         |
|                                       | (If score = 0, total = 0 and go to <i>Grossmt</i> )                       | _____        | _____         |
| 3                                     | Ball bearing 2nd finger and thumb   | _____        | _____         |
| 4                                     | Ball bearing 1st finger and thumb   | _____        | _____         |
| 5                                     | Marble 2nd finger and thumb   | _____        | _____         |
| 6                                     | Marble 1st finger and thumb   | _____        | _____         |
| Coefficient of reproducibility = 0.99 |   |              |               |
| Coefficient of scalability = 0.98     |   |              |               |
| <b>Total</b>                          |   | Left = _____ | Right = _____ |
| <i>Grossmt (Gross movement)</i>       |   |              |               |
| 1                                     | Place hand behind head  | _____        | _____         |
|                                       | (If score = 3, total = 9 and finish)                                      | _____        | _____         |
| 2                                     | (If score = 0, total = 0 and finish)                                      | _____        | _____         |
| 3                                     | Place hand on top of head   | _____        | _____         |
| 4                                     | Hand to mouth   | _____        | _____         |
| Coefficient of reproducibility = 0.98 |   |              |               |
| Coefficient of scalability = 0.97     |   |              |               |
| <b>Total</b>                          |   | Left = _____ | Right = _____ |



## **APPENDIX 14**

### **Barthel Index (BI)**

#### **Feeding**

10 = Independent Patient can feed self when someone puts the food within reach. Must be able to put on mechanical device if needed, cut up the food, use salt and pepper, spread butter, etc. Must accomplish this in a reasonable time. Must eat normal foods (not just soft foods).

5 = Some help in necessary Help cutting up food, etc. but can feed self. Soft/pureed ok

0 = Dependent Cannot do at least 50% of activity by self.

#### **Transfer (from bed to chair or wheel-chair)**

15 = Independent in all phases of this activity. Patient can safely approach the bed in wheelchair, lock brakes, lift footrests, move to bed, lie down, come to a sitting position on the side of the bed, change wheelchair position if necessary, and return to the wheelchair. Transfer may be from bed to regular chair and back if wheelchair is not needed.

10 = Minor help Either minimal help is needed in some step of this activity or patient needs to be reminded or supervised for safety.

5 = Major help Can come to a sitting position without the help of another person but needs to be lifted out of bed, or transfers, but with a great deal of help.

0 = Dependent Patient has no sitting balance, in addition to needing to be lifted from bed.

### Grooming

5 = Independent Can wash hands and face, comb hair, clean teeth. Males can shave using any kind of razor but must put in blade or plug in razor without help. Females must put on own make-up, but need not braid or style hair. Implements may be laid out for patient by helper.

0 = Dependent Needs help with grooming.

### Getting on and off toilet

10 = Independent Can get on and off toilet, fasten and unfasten clothes, prevent soiling of clothes and use toilet paper without help. May use bar for support. If bed pan is used, must be able to position, empty and clean it.

5 = Needs some help Needs help for balance or with clothes or with toilet paper.

0 = Dependent Cannot manage without major help in all steps of toileting.

### Bathing self

5 = Independent Can use a bath tub or shower or a sponge bath. Must do all steps alone.

0 = Dependent Needs supervision or assistance with bathing.

### Walking on a level surface (or self-propels wheelchair)

15 = Independent Can walk at least 50 yards without help or supervision. May wear prostheses, use crutches, canes or a walker, but not one with wheels. Must be able to lock and unlock braces, and dispose of aids when standing or sitting.

10 = Walks with help. Needs help or supervision in any of the above but can walk at least 50 yards with a little help.



5 = Able to propel a wheelchair Patient cannot ambulate but can propel a wheelchair 50 yards. Can go around corners, turn around, manoeuvre the chair to a table, bed, toilet, etc. (Do not assign this score if patient fits either criteria above for walking).

0 = Dependent Cannot meet any of the above criteria.

#### Ascending and descending stairs

10 = Independent Can go up and down a flight of stairs safely without help or supervision. May use handrail, and must be able to carry canes or crutches when needed.

5 = Needs some help Needs help with or supervision, but can ascend and descend stairs.

0 = Dependent Cannot meet either of the above criteria.

#### Dressing and undressing

10 = Independent Can put on, remove and fasten all clothing and tie shoe laces. Includes putting on and removing and fastening prescribed garments (braces, girdles). Women need not be scored on use of bra. Clothes such as front fastening dresses and loafers can be worn.

5 = Needs some help Needs help in putting on and removing or fastening any clothing. Must do at least half the work by self. Must accomplish this in a reasonable time.

0 = Dependent Cannot meet either of the above criteria

#### Continence of bowels (in preceding week)

10 = Independent Able to control bowels and has no accidents. Able to use own enema.

5 = Has occasional accident or needs help. Has accident once a week. Needs help w/enema

0 = Incontinent Has accidents more than once a week or must be given enema by nurse

Continence of bladder (in preceding week)

10 = Independent Able to control bladder day and night. Able to handle own bag or catheter.

5 = Has occasional accidents or needs help. Has accidents (one per 24 hours) or needs help

0 = Incontinent Accidents more often than once per 24 hours..

Total Score \_\_\_\_\_(Maximum = 100 points)

## APPENDIX 15

### Berg Balance Scale (BBS)

Score 0 – 4 (According to Berg Balance Protocol)

#### Item Description:

|  |       |
|--|-------|
| Sitting to standing                    | _____ |
| Standing unsupported                   | _____ |
| Sitting unsupported                    | _____ |
| Standing to sitting                    | _____ |
| Transfers                              | _____ |
| Standing with eyes closed              | _____ |
| Standing with feet together            | _____ |
| Reaching forward with outstretched arm | _____ |
| Retrieving object from the floor       | _____ |
| Turning to look behind                 | _____ |
| Turning 360 degrees                    | _____ |
| Placing alternate foot on stool        | _____ |
| Standing with one foot in front        | _____ |
| Standing on one foot                   | _____ |

TOTAL \_\_\_\_\_/56



## **APPENDIX 16**

### **Chedoke McMaster Postural Control Score**

#### **CIRCLE APPROPRIATE TASKS /STAGE ACHIEVED (Begin at stage 4)**

##### **Stage 1:**

Unable to demonstrate at least two of the stage 2 tasks

##### **Stage 2:**

Task1: Facilitated log roll to side lying

Task2: Resistance to trunk rotation

Task3: Static righting with facilitation

##### **Stage 3:**

Task1: Log rolling to side lying

Task2: Move forward and backward

Task3: Remain upright for 5 seconds

##### **Stage 4:**

Task1: Segmental Rolling to side-lying

Task2: Static righting

Task3: Stand

##### **Stage 5:**

Task1: Dynamic righting side to side, feet on floor

Task2: Standing with equal weight bearing

Task3: Step forward onto weak leg, transfer weight

##### **Stage 6:**

Task1: Dynamic righting backward and sideways with displacement, feet off floor

Task2: On weak leg 5 seconds

Task3: Sideways braiding for 2 metres

Stage 7:

Task1: Abduction of strong leg

Task2: Tandem walking 2 metres in 5 seconds

Task3: Walk on toes 2 metres

## **APPENDIX 17**

### **Chedoke McMaster Shoulder Impairment Score**

With client in sitting, observe the position of the scapular spine and the inferior angle of the scapular of the weaker side in relation to the stronger side.

In supine, with weak arm in a neutral position,

With elbow extended, flex the shoulder and note whether there is less than 90 degrees of painfree range

With elbow flexed to 90 degrees, abduct the shoulder and note whether there is less than 90 degrees of painfree range

With elbow flexed, externally rotate the shoulder and note whether there is less than 90 degrees of painfree range

Prognostic indicators are:

The arm is in a low stage of recovery (1 or 2)

The scapular is malaligned

Loss of range of movement with flexion or abduction less than 90 degrees, or external rotation less than 60 degrees

### **CIRCLE APPROPRIATE STAGE:**

Stage 1:

Constant severe arm and shoulder pain with pain pathology in more than just the shoulder

Stage 2:

Intermittent, severe arm and shoulder pain with pathology in more than just the shoulder

Stage 3:

Constant shoulder pain with pathology in just the shoulder

Stage 4:

Intermittent shoulder pain with pathology in just the shoulder

Stage 5:

Shoulder pain is noted during testing, but the functional activities that the client normally performs are not affected by the pain

Stage 6:

No shoulder pain, but at least one prognostic indicator is present

Stage 7:

Shoulder pain and prognostic indicators are absent



## APPENDIX 18

EQ5VAS

**EQ-5D VAS**

Patient Identification: \_\_\_\_\_

Visit: Baseline ☐ 6 Month ☐ 12 Month ☐

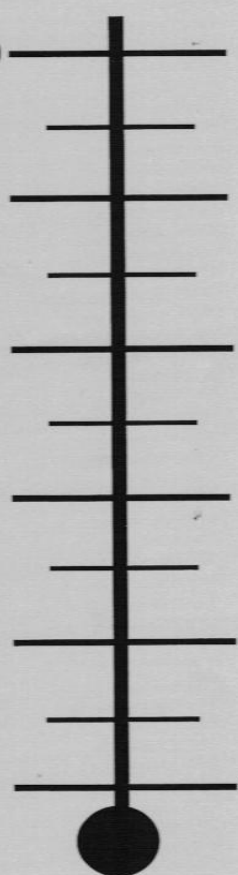
**BEST OF HEALTH**

**Your Health Today**

Draw a line from this box to the place on the scale that shows how good or bad your health is today

10 = the best of health  
0 = the worst health

10  
9  
8  
7  
6  
5  
4  
3  
2  
1  
0





## APPENDIX 19

### Functional Independence Measure (FIM)

#### Scoring:

1=Maximal Assistance

2=Total Assistance

3=Moderate Assistance

4=Minimal Assistance

5=Supervision

6=Modified Independence

7=Complete Independence

#### MOTOR COMPONENT

##### Self Care:

Eating \_\_\_\_\_

Grooming \_\_\_\_\_

Bathing \_\_\_\_\_

Dressing – upper \_\_\_\_\_

Dressing – lower \_\_\_\_\_

Toileting \_\_\_\_\_

#### MOTOR COMPONENT

##### Sphincter Control:

Bladder Management \_\_\_\_\_

Bowel Management \_\_\_\_\_

#### MOTOR COMPONENT

##### Transfers:

Bed, Chair, Wheelchair \_\_\_\_\_

Toilet \_\_\_\_\_

Bath/ Shower \_\_\_\_\_

MOTOR COMPONENT

Locomotion:

Walk or Wheelchair \_\_\_\_\_

Stairs \_\_\_\_\_

MOTOR COMPONENT SUBSCORE: \_\_\_\_\_ /91

COGNITIVE COMPONENT

Comprehension:

Auditory or Visual \_\_\_\_\_

COGNITIVE COMPONENT

Expression:

Verbal or Non-verbal \_\_\_\_\_

COGNITIVE COMPONENT

Social Cognition:

Social Interaction \_\_\_\_\_

Problem Solving \_\_\_\_\_

Memory \_\_\_\_\_

COGNITIVE COMPONENT SUBSCORE: \_\_\_\_\_ /35

TOTAL FIM SCORE: \_\_\_\_\_ /126

## APPENDIX 20

### Hospital Anxiety and Depression Scale (HADS)

| HAD Scale   |                  |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
|---|------------------|---|-------------------|---|----------------------------|---|------------|---|--------------------|---|-------------------|---|---------------|---|---------------|---|---------------------------------|---|------------------------|---|-----------------------------------|---|------------|---|---------------------------|---|-----------------------|---|----------------------------|---|------------|---|--------------------------|---|-------------------|---|-------------------------------------|---|-------------------|---|------------|---|-----------|---|-----------|---|------------------|---|------------|---|---------|---|-----------|---|------------|---|--|---------------------|---|------------|---|-----------|---|------------|---|------------|---|--------------|---|-------------|---|------------|---|------------|---|---------------------------------------|---|-----------------------------------|---|----------------------------------|---|------------------|---|-------------|---|---------------|---|------------|---|-----------------------|---|----------------------------|---|--------------------------------|---|---------------|---|-------------------|---|-------------|---|----------------|---|------------|---|-------|---|-----------|---|-----------|---|-------------|---|
| Patient Identification: _____   |                  |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Visit: Baseline <input type="checkbox"/> 6 Month <input type="checkbox"/> 12 Month <input type="checkbox"/>   |                  |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| <p><i>Read each item and circle the reply which comes closest to how you have been feeling in the past week.</i></p> <p><i>Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.</i></p>   |                  |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| <p><b>I feel tense or 'wound up':</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Most of the time</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>A lot of the time</td><td style="text-align: center;">2</td></tr> <tr><td>Time to time, Occasionally</td><td style="text-align: center;">1</td></tr> <tr><td>Not at all</td><td style="text-align: center;">0</td></tr> </table> <p><b>I still enjoy the things I used to enjoy:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Definitely as much</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Not quite so much</td><td style="text-align: center;">1</td></tr> <tr><td>Only a little</td><td style="text-align: center;">2</td></tr> <tr><td>Hardly at all</td><td style="text-align: center;">3</td></tr> </table> <p><b>I get a sort of frightened feeling as if something awful is about to happen:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Very definitely and quite badly</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>Yes, but not too badly</td><td style="text-align: center;">2</td></tr> <tr><td>A little, but it doesn't worry me</td><td style="text-align: center;">1</td></tr> <tr><td>Not at all</td><td style="text-align: center;">0</td></tr> </table> <p><b>I can laugh and see the funny side of things:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">As much as I always could</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Not quite so much now</td><td style="text-align: center;">1</td></tr> <tr><td>Definitely not so much now</td><td style="text-align: center;">2</td></tr> <tr><td>Not at all</td><td style="text-align: center;">3</td></tr> </table> <p><b>Worrying thoughts go through my mind:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">A great deal of the time</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>A lot of the time</td><td style="text-align: center;">2</td></tr> <tr><td>From time to time but not too often</td><td style="text-align: center;">1</td></tr> <tr><td>Only occasionally</td><td style="text-align: center;">0</td></tr> </table> <p><b>I feel cheerful:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Not at all</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>Not often</td><td style="text-align: center;">2</td></tr> <tr><td>Sometimes</td><td style="text-align: center;">1</td></tr> <tr><td>Most of the time</td><td style="text-align: center;">0</td></tr> </table> <p><b>I can sit at ease and feel relaxed:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Definitely</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Usually</td><td style="text-align: center;">1</td></tr> <tr><td>Not often</td><td style="text-align: center;">2</td></tr> <tr><td>Not at all</td><td style="text-align: center;">3</td></tr> </table> | Most of the time | 3 | A lot of the time | 2 | Time to time, Occasionally | 1 | Not at all | 0 | Definitely as much | 0 | Not quite so much | 1 | Only a little | 2 | Hardly at all | 3 | Very definitely and quite badly | 3 | Yes, but not too badly | 2 | A little, but it doesn't worry me | 1 | Not at all | 0 | As much as I always could | 0 | Not quite so much now | 1 | Definitely not so much now | 2 | Not at all | 3 | A great deal of the time | 3 | A lot of the time | 2 | From time to time but not too often | 1 | Only occasionally | 0 | Not at all | 3 | Not often | 2 | Sometimes | 1 | Most of the time | 0 | Definitely | 0 | Usually | 1 | Not often | 2 | Not at all | 3 | <p><b>I feel as if I am slowed down:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Nearly all the time</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>Very often</td><td style="text-align: center;">2</td></tr> <tr><td>Sometimes</td><td style="text-align: center;">1</td></tr> <tr><td>Not at all</td><td style="text-align: center;">0</td></tr> </table> <p><b>I get a sort of frightened feeling like 'butterflies' in the stomach:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Not at all</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Occasionally</td><td style="text-align: center;">1</td></tr> <tr><td>Quite often</td><td style="text-align: center;">2</td></tr> <tr><td>Very often</td><td style="text-align: center;">3</td></tr> </table> <p><b>I have lost interest in my appearance:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Definitely</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>I don't take so much care as I should</td><td style="text-align: center;">2</td></tr> <tr><td>I may not take quite as much care</td><td style="text-align: center;">1</td></tr> <tr><td>I take just as much care as ever</td><td style="text-align: center;">0</td></tr> </table> <p><b>I feel restless as if I have to be on the move:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Very much indeed</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>Quite a lot</td><td style="text-align: center;">2</td></tr> <tr><td>Not very much</td><td style="text-align: center;">1</td></tr> <tr><td>Not at all</td><td style="text-align: center;">0</td></tr> </table> <p><b>I look forward with enjoyment to things:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">As much as I ever did</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Rather less than I used to</td><td style="text-align: center;">1</td></tr> <tr><td>Definitely less than I used to</td><td style="text-align: center;">2</td></tr> <tr><td>Hardly at all</td><td style="text-align: center;">3</td></tr> </table> <p><b>I get sudden feelings of panic:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Very often indeed</td><td style="width: 20%; text-align: center;">3</td></tr> <tr><td>Quite often</td><td style="text-align: center;">2</td></tr> <tr><td>Not very often</td><td style="text-align: center;">1</td></tr> <tr><td>Not at all</td><td style="text-align: center;">0</td></tr> </table> <p><b>I can enjoy a good book or radio or TV program:</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 80%;">Often</td><td style="width: 20%; text-align: center;">0</td></tr> <tr><td>Sometimes</td><td style="text-align: center;">1</td></tr> <tr><td>Not often</td><td style="text-align: center;">2</td></tr> <tr><td>Very seldom</td><td style="text-align: center;">3</td></tr> </table> | Nearly all the time | 3 | Very often | 2 | Sometimes | 1 | Not at all | 0 | Not at all | 0 | Occasionally | 1 | Quite often | 2 | Very often | 3 | Definitely | 3 | I don't take so much care as I should | 2 | I may not take quite as much care | 1 | I take just as much care as ever | 0 | Very much indeed | 3 | Quite a lot | 2 | Not very much | 1 | Not at all | 0 | As much as I ever did | 0 | Rather less than I used to | 1 | Definitely less than I used to | 2 | Hardly at all | 3 | Very often indeed | 3 | Quite often | 2 | Not very often | 1 | Not at all | 0 | Often | 0 | Sometimes | 1 | Not often | 2 | Very seldom | 3 |
| Most of the time  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| A lot of the time   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Time to time, Occasionally  | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Definitely as much  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not quite so much   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Only a little   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Hardly at all   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very definitely and quite badly   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Yes, but not too badly  | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| A little, but it doesn't worry me   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| As much as I always could   | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not quite so much now   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Definitely not so much now  | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| A great deal of the time  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| A lot of the time   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| From time to time but not too often   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Only occasionally   | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not often   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Sometimes   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Most of the time  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Definitely  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Usually   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not often   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Nearly all the time   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very often  | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Sometimes   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Occasionally  | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Quite often   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very often  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Definitely  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| I don't take so much care as I should   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| I may not take quite as much care   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| I take just as much care as ever  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very much indeed  | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Quite a lot   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not very much   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| As much as I ever did   | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Rather less than I used to  | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Definitely less than I used to  | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Hardly at all   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very often indeed   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Quite often   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not very often  | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not at all  | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Often   | 0                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Sometimes   | 1                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Not often   | 2                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| Very seldom   | 3                |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |
| <p>For hospital use only</p> <p style="margin: 0;">A _____ D _____</p>  |                  |   |                   |   |                            |   |            |   |                    |   |                   |   |               |   |               |   |                                 |   |                        |   |                                   |   |            |   |                           |   |                       |   |                            |   |            |   |                          |   |                   |   |                                     |   |                   |   |            |   |           |   |           |   |                  |   |            |   |         |   |           |   |            |   |  |                     |   |            |   |           |   |            |   |            |   |              |   |             |   |            |   |            |   |                                       |   |                                   |   |                                  |   |                  |   |             |   |               |   |            |   |                       |   |                            |   |                                |   |               |   |                   |   |             |   |                |   |            |   |       |   |           |   |           |   |             |   |



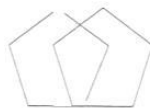
## APPENDIX 21

### MMSE

| MMSE   |                          |
|--|--------------------------|
| Patient Identification:  |                          |
| Visit : Baseline   | <input type="checkbox"/> |
| 6 Month  | <input type="checkbox"/> |
| 12 Month   | <input type="checkbox"/> |
| Orientation:   |                          |
| What is the Year ? Season ? Date ? Day ? Month ? (score 1 point for each correct answer)   | ____/5                   |
| Where is the name of the Country ? State ? City ? Hospital ? Ward ? (score 1 point for each correct answer)  | ____/5                   |
| Registration:  |                          |
| Name three objects; (eg ball, flag, tree) taking one second to say each. Then ask the patient to repeat all three object you have named. (Score 1 point for each item repeated.) | ____/3                   |
| If the patient is not successful, repeat them until he/she learns all three.<br>(This is preparation for the recall item below).   |                          |
| Attention and calculation:   |                          |
| Ask the patient to subtract 7 from 100, and then 7 from the result – repeat this five times.<br>(score 1 point each time a correct subtraction is performed)                     | ____/5                   |
| Recall:  |                          |
| Ask for the three objects repeated in the registration test. (score 1 point for each correct answer)   | ____/3                   |
| Language:  |                          |
| Show a pencil and a watch and ask the subject to name them. (score 1 point for each correct answer)  | ____/2                   |
| Repeat the following: “no ifs, ands or buts”. (score 1 point for if answered correctly)  | ____/1                   |
| A three-stage command, “Take this piece of paper in your right hand; fold it in half and put it on the floor.”<br>(score 1 point for each command performed correctly)           | ____/3                   |
| Point below to “CLOSE YOUR EYES” and ask the patient to obey what is written.<br>(Score 1 point if performed correctly)  | ____/1                   |
| Ask the patient to write a sentence below.<br>(Score 1 point if the sentence is sensible and has a verb and a subject)   | ____/1                   |
| Ask the patient to copy the diagram below<br>(Score 1 point if performed correctly)  | ____/1                   |
| TOTAL SCORE  | ____/30                  |

### CLOSE YOUR EYES

SENTENCE \_\_\_\_\_







## APPENDIX 22

### MOS 36-Item Short Form Health Survey (SF-36)

| <b>SF-36 v2</b>  |   |                                      |  |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
|--|---|--------------------------------------|--|--|-----------------------|---|---|--------------------------------------|--|---|-----------------------|---|-----------------------|--|-----------------------|-----------------------|-----------------------|--|-----------------------|-----------------------|-----------------------|---------------------------------------|-----------------------|---|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|---|-----------------------|-----------------------|-----------------------|-----------------------------|-----------------------|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|------------------------------|-----------------------|-----------------------|-----------------------|---------------------------------|-----------------------|-----------------------|-----------------------|
| Patient Identification:  |   |                                      |  |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| Visit: Baseline <input type="checkbox"/> 6 Month <input type="checkbox"/> 12 Month <input type="checkbox"/>  |   |                                      |  |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <p>1. In general, would you say your health is: (Please tick the circle that best describes your answer.)</p> <table style="width: 100%; text-align: center;"> <tr> <td>Excellent</td> <td>Very Good</td> <td>Good</td> <td>Fair</td> <td>Poor</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> </table>   |   |                                      |  |  |                       | Excellent                               | Very Good                                   | Good                                 | Fair                                       | Poor  | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> | <input type="radio"/>  | <input type="radio"/> |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| Excellent  | Very Good                                   | Good                                 | Fair                                       | Poor                                   |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <input type="radio"/>  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <p>2. Compared to one year ago, how would you rate your health in general now?</p> <table style="width: 100%; text-align: center;"> <tr> <td>Much better<br/>now than one<br/>year ago</td> <td>Somewhat better<br/>now than one<br/>year ago</td> <td>About the<br/>same as one<br/>year ago</td> <td>Somewhat worse<br/>now than one<br/>year ago</td> <td>Much worse<br/>now than one<br/>year ago</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> </table>  |   |                                      |  |  |                       | Much better<br>now than one<br>year ago | Somewhat better<br>now than one<br>year ago | About the<br>same as one<br>year ago | Somewhat worse<br>now than one<br>year ago | Much worse<br>now than one<br>year ago  | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> | <input type="radio"/>  | <input type="radio"/> |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| Much better<br>now than one<br>year ago  | Somewhat better<br>now than one<br>year ago | About the<br>same as one<br>year ago | Somewhat worse<br>now than one<br>year ago | Much worse<br>now than one<br>year ago |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <input type="radio"/>  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <p>3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Click on a circle on each line.]</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Yes,<br/>limited<br/>a lot</th> <th style="text-align: center;">Yes,<br/>limited<br/>a little</th> <th style="text-align: center;">No, not<br/>limited<br/>at all</th> </tr> </thead> <tbody> <tr> <td>a. Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>c. Lifting or carrying groceries</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>d. Climbing several flights of stairs</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>e. Climbing one flight of stairs</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>f. Bending, kneeling, or stooping</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>g. Walking more than a mile</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>h. Walking several hundred yards</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>i. Walking one hundred yards</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>j. Bathing or dressing yourself</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> </tbody> </table> |   |                                      |  |  |                       |   | Yes,<br>limited<br>a lot                    | Yes,<br>limited<br>a little          | No, not<br>limited<br>at all               | a. Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> | b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | c. Lifting or carrying groceries         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | d. Climbing several flights of stairs | <input type="radio"/> | <input type="radio"/>                                   | <input type="radio"/> | e. Climbing one flight of stairs | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | f. Bending, kneeling, or stooping   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | g. Walking more than a mile | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | h. Walking several hundred yards | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | i. Walking one hundred yards | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | j. Bathing or dressing yourself | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
|  | Yes,<br>limited<br>a lot                    | Yes,<br>limited<br>a little          | No, not<br>limited<br>at all               |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| a. Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| c. Lifting or carrying groceries   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| d. Climbing several flights of stairs  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| e. Climbing one flight of stairs   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| f. Bending, kneeling, or stooping  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| g. Walking more than a mile  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| h. Walking several hundred yards   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| i. Walking one hundred yards   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| j. Bathing or dressing yourself  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      |  |                       |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| <p>4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">All of<br/>the time</th> <th style="text-align: center;">Most of<br/>the time</th> <th style="text-align: center;">Some of<br/>the time</th> <th style="text-align: center;">A little of<br/>the time</th> <th style="text-align: center;">None of<br/>the time</th> </tr> </thead> <tbody> <tr> <td>a. Cut down on the amount of time you spent on work or other activities</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>b. Accomplished less than you would like</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>c. Were limited in the kind of work or other activities</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>d. Had difficulty performing the work or other activities (for example, it took extra effort)</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> </tbody> </table>   |   |                                      |  |  |                       |   | All of<br>the time                          | Most of<br>the time                  | Some of<br>the time                        | A little of<br>the time   | None of<br>the time   | a. Cut down on the amount of time you spent on work or other activities | <input type="radio"/> | <input type="radio"/>  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | b. Accomplished less than you would like | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>                 | <input type="radio"/> | c. Were limited in the kind of work or other activities | <input type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | d. Had difficulty performing the work or other activities (for example, it took extra effort) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>       | <input type="radio"/> |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
|  | All of<br>the time                          | Most of<br>the time                  | Some of<br>the time                        | A little of<br>the time                | None of<br>the time   |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| a. Cut down on the amount of time you spent on work or other activities  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  | <input type="radio"/> |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| b. Accomplished less than you would like   | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  | <input type="radio"/> |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| c. Were limited in the kind of work or other activities  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  | <input type="radio"/> |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |
| d. Had difficulty performing the work or other activities (for example, it took extra effort)  | <input type="radio"/>                       | <input type="radio"/>                | <input type="radio"/>                      | <input type="radio"/>                  | <input type="radio"/> |   |   |                                      |  |   |                       |   |                       |  |                       |                       |                       |  |                       |                       |                       |                                       |                       |   |                       |                                  |                       |                       |                       |   |                       |                       |                       |                             |                       |                       |                       |                                  |                       |                       |                       |                              |                       |                       |                       |                                 |                       |                       |                       |

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

|  | All of<br>the time    | Most of<br>the time   | Some of<br>the time   | A little of<br>the time | None of<br>the time   |
|--|-----------------------|-----------------------|-----------------------|-------------------------|-----------------------|
| a. Cut down on the <i>amount of time</i> you spent on work or other activities | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| b. <i>Accomplished less</i> than you would like                                | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| c. Did work or activities <i>less carefully</i> than usual                     | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |

6. During the *past 4 weeks*, to what extent has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups?

| Not at all            | Slightly              | Moderately            | Quite a bit           | Extremely             |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

7. How much *bodily pain* have you had during the *past 4 weeks*?

| None                  | Very Mild             | Mild                  | Moderate              | Severe                | Very Severe           |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both outside the home and housework)?

| Not at all            | A little bit          | Moderately            | Quite a bit           | Extremely             |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

9. These questions are about how you feel and how things have been with you *during the past 4 weeks*. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*...

|  | All of<br>the time    | Most of<br>the time   | Some of<br>the time   | A little of<br>the time | None of<br>the time   |
|--|-----------------------|-----------------------|-----------------------|-------------------------|-----------------------|
| a. Did you feel full of life?  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| b. Have you been very nervous?   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| c. Have you felt so down in the dumps that nothing could cheer you up? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| d. Have you felt calm and peaceful?                                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| e. Did you have a lot of energy?                                       | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| f. Have you felt downhearted and depressed?                            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| g. Did you feel worn out?  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| h. Have you been happy?  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |
| i. Did you feel tired?   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> |

10. During the past 4 weeks, how much of the time has your *physical health or emotional problems* interfered with your social activities (like visiting friends, relatives, etc.)?

All of  
the time  
☐

Most of  
the time  
☐

Some of  
the time  
☐

A little of  
the time  
☐

None of  
the time  
☐

11. How TRUE or FALSE is *each* of the following statements for you?

|   | Definitely<br>true    | Mostly<br>true        | Don't<br>Know         | Mostly<br>false       | Definitely<br>false   |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| a. I seem to get sick a little easier than other people | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. I am as healthy as anybody I know                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c. I expect my health to get worse                      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d. My health is excellent                               | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |



## APPENDIX 23

### Rankin Scale

| Modified Rankin Scale  |  |
|--|--|
| Patient Identification:  |  |
| Visit : Baseline <input type="checkbox"/> 6 Month <input type="checkbox"/> 12 Month <input type="checkbox"/> |  |
| Please tick the ONE box which best describes the patient's health today:                                     |  |
| <input type="checkbox"/>   | Grade 0 No symptoms at all.  |
| <input type="checkbox"/>   | Grade 1 No significant disability despite symptoms<br>(Able to carry out all usual duties and activities)                  |
| <input type="checkbox"/>   | Grade 2 Slight disability<br>(Unable to carry out all previous activities, but able to attend to own affairs w/out assist) |
| <input type="checkbox"/>   | Grade 3 Moderate disability<br>(Requires some help, but able to walk without assistance)                                   |
| <input type="checkbox"/>   | Grade 4 Moderate, severe disability<br>(Unable to walk w/out assistance, and unable to attend to own bodily needs)         |
| <input type="checkbox"/>   | Grade 5 Severe disability<br>(Bedridden, incontinent and requires constant nursing care and attention)                     |



## APPENDIX 24

### Scandinavian Stroke Score

888

STROKE

Vol. 16, No. 5, SEPTEMBER-OCTOBER 1985

TABLE 1 Initial Prognostic and Long-term Functional Scores Used for the Multicenter Hemodilution Trial

|  | Score | Prognostic score         | Long-term score          |
|--|-------|--------------------------|--------------------------|
| Consciousness  |       |                          |                          |
| fully conscious                                      | 6     |                          |                          |
| somnolent; can be awakened to full consciousness     | 4     | <input type="checkbox"/> |                          |
| reacts to verbal command, but is not fully conscious | 2     |                          |                          |
| Eye movements  |       |                          |                          |
| no gaze palsy  | 4     |                          |                          |
| gaze palsy present                                   | 2     | <input type="checkbox"/> |                          |
| conjugate eye deviation                              | 0     |                          |                          |
| Arm, motor power*                                    |       |                          |                          |
| raises arm with normal strength                      | 6     |                          |                          |
| raises arm with reduced strength                     | 5     |                          |                          |
| raises arm with flexion in elbow                     | 4     | <input type="checkbox"/> | <input type="checkbox"/> |
| can move, but not against gravity                    | 2     |                          |                          |
| paralysis  | 0     |                          |                          |
| Hand, motor power*                                   |       |                          |                          |
| normal strength                                      | 6     |                          |                          |
| reduced strength in full range                       | 4     |                          |                          |
| some movement, fingertips do not reach palm          | 2     |                          | <input type="checkbox"/> |
| paralysis  | 0     |                          |                          |
| Leg, motor power                                     |       |                          |                          |
| normal strength                                      | 6     |                          |                          |
| raises straight leg with reduced strength            | 5     |                          |                          |
| raises leg with flexion of knee                      | 4     | <input type="checkbox"/> | <input type="checkbox"/> |
| can move, but not against gravity                    | 2     |                          |                          |
| paralysis  | 0     |                          |                          |
| Orientation  |       |                          |                          |
| correct for time, place and person                   | 6     |                          |                          |
| 2 of these   | 4     |                          | <input type="checkbox"/> |
| 1 of these   | 2     |                          |                          |
| completely disorientated                             | 0     |                          |                          |
| Speech   |       |                          |                          |
| no aphasia   | 10    |                          |                          |
| limited vocabulary or incoherent speech              | 6     |                          | <input type="checkbox"/> |
| more than yes/no, but not longer sentences           | 3     |                          |                          |
| only yes/no or less                                  | 0     |                          |                          |
| Facial palsy   |       |                          |                          |
| none/dubious   | 2     |                          | <input type="checkbox"/> |
| present  | 0     |                          |                          |
| Gait   |       |                          |                          |
| walks 5 m without aids                               | 12    |                          |                          |
| walks with aids                                      | 9     |                          |                          |
| walks with help of another person                    | 6     |                          | <input type="checkbox"/> |
| sits without support                                 | 3     |                          |                          |
| bedridden/wheelchair                                 | 0     |                          |                          |
| Maximal score  |       | 22                       | 48                       |

\*Motor power is assessed only on the affected side.

\*Motor power is assessed only on the affected side.





## **APPENDIX 25**

Research protocol

### **SRO TRIAL RESEARCH ASSISTANT'S PROTOCOL**

#### **SUBJECT SOURCES:**

##### **A**

Collect DGM referrals from DGM Secretary 5th floor Ainslee House  
(Murray St); Double check in with RA (down the corridor, or page 2209) re: other  
DGM inpts (should be left with DGM Sec @ 1); Sort through referrals for any  
relevant stroke pts over 60years old and with no history of dementia; Locate pts  
within hospital

#### **CONSENT PTS**

##### **B**

On 8A, check red file at Ward Clerk's station for RPH Shenton Park Campus Ward 2  
referrals (listed on white paper). These may have originated from anywhere at RPH  
Wellington ST, not just 8A. Find out if anyone referred has been accepted for rehab  
at Ward 2, and whether or not their diagnosis is stroke. This may involve chasing up  
the original referral (on it's ward of origin) on a Thursday if you do not sight it on  
Wednesday or ringing the Ward 2 Clerk directly

Locate pts within hospital

#### **CONSENT PTS**

##### **C**

Get copy of 8A list post- Wednesday morning ward meeting and discuss with  
physios to identify new patients and current management – ie rehab or discharge  
planning

Check new referrals to DGM from mtg (should be seen straight after mtg by DGM Reg and Shenton Park. Do not consider those pts going straight to GEM with view to discharge home from there

CONSENT PATIENTS

POST-PATIENT CONSENT

Document consent in headsheet

Collect Baseline Data (liaising with AHS where appropriate)

Leave copy of pt consent and pt info sheet along with patient diary in a plastic sleeve in the front of the headsheet. Staple it so diary doesn't get lost and write "For Allied Health Staff at \_\_\_\_\_ Hospital" (Mercy, Bentley, Swans or Shenton as appropriate) on the plastic sleeve

Establish who is pt's caregiver with pt

Discuss trial with caregiver (over phone or in person)

Arrange outpatient appointment for 6 months time (at neuro outpatient clinic on 7th floor) on a Wednesday morning and record in Diary

Contact each peripheral hospital re: discharged pts to keep our list current, and to thereby flag completed diaries for collection

## APPENDIX 26

### Patient information sheet and consent



**Department of Health**  
Government of Western Australia  
East Metropolitan Health Service

**Royal Perth Hospital**

HEIN 13 393 250 709



**STUDY TITLE:** Outcomes of different rehabilitation approaches in patients post-stroke

#### **PATIENT INFORMATION SHEET**

##### **Introduction**

Stroke is a common illness in most western countries requiring rehabilitation. This rehabilitation is complicated and may involve many professionals. The best recovery of daily function is the ultimate goal, and it is important that patients are provided with every opportunity to achieve their greatest potential.

There are many different approaches to rehabilitation and little scientific evidence to favor one approach over another. Many studies have noted that although patients having suffered similar types of strokes originally, their functional outcome is quite variable. In Perth, there are a number of different types of facilities that offer stroke rehabilitation. The purpose of this research is to see whether the level of recovery differs between rehabilitation facilities.

You have been asked to participate in this study because you have had a stroke requiring further rehabilitation.

##### **What does the trial involve?**

Whether you volunteer for this research or not, the rehabilitation you receive may be at Royal Perth Hospital – Shenton Park Campus or another facility closer to your home. Your overall care will be under the guidance of a neurologist at Shenton Park or a geriatrician at the other facilities. Both types of facility provide a wide range of therapies including physiotherapy, occupational therapy and speech pathology.

If you volunteer for this research, you will take a treatment diary to your rehabilitation facility, and the rehabilitation staff will be required to fill out details of the time spent with you during your stay there. Your day to day activities may also be periodically monitored by an independent observer. Your progress will then be assessed at 6 and 12 months after transfer at follow-up appointments. By this time, you may have already gone home and if necessary, transport may be arranged to these appointments. Assessments will last approximately 1 hour and will include the types of activities you perform in your everyday life (for example, how you get out of bed, sit and balance). You will also be asked questions about how you think you have progressed in your recovery, including questions regarding your mental and physical state and how you are coping after stroke. Some of these questions will be on questionnaires that will be posted to you for completion at six months and twelve months post-stroke. The postal questionnaires will take a total of one half hour to complete.

##### **Benefits and Risks**

There are no benefits or risks for you in the trial, as you will receive rehabilitation whether or not you participate in the study. You will however be providing valuable information for doctors and therapists of future stroke patients by participating.

**Wellington Street Campus**  
Box X2213 GPO, Perth 6847  
Western Australia

**Telephone: (08) 9224 2244**  
Facsimile: (08) 9224 3511  
T.T.Y. Line: (08) 9224 7016

**Shenton Park Campus** **Telephone: (08) 9382 7171**  
6 Selby Street, Shenton Park 6008  
Western Australia Facsimile: (08) 9382 7351



**Department of Health**  
Government of Western Australia  
East Metropolitan Health Service

**Royal Perth Hospital**

ABN 13 993 250 709



**Withdrawal from the study**

Your participation in the study is entirely voluntary. You may withdraw from the study at any time without explanation and without it affecting your treatment.

**Further information**

This project has been approved by the Royal Perth Hospital Ethics Committee.  
Additional information is available from the Investigator Diane Dennis (Tel: 9371 6319)  
or Clin Prof A Millar, Chairman of the Committee (Tel: 9224 2199)

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**Telephone: (08) 9382 7171**  
Facsimile: (08) 9382 7351



Department of Health  
Government of Western Australia  
East Metropolitan Health Service

Royal Perth Hospital

ABN 12 963 250 708



**STUDY TITLE:** Outcomes of different rehabilitation approaches in  
patients post-stroke

### PATIENT CONSENT FORM

I,.....agree to participate in the above  
study. I have read and understood the attached Information Sheet and I have retained  
a copy of the signed document. I have been given the opportunity to ask questions  
about the study by the investigator or team doctor. I understand that I may withdraw  
from the study at any time without affecting any future medical treatment, or the  
treatment of the condition which is the subject of the trial.

Signed.....Date.....

Signature of team doctor or investigator.....Date.....

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Box X2213 GPO, Perth 6847 Facsimile: (08) 9224 3511  
Western Australia T.T.Y. Line: (08) 9224 7016

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5 Selby Street, Shenton Park 6008 Facsimile: (08) 9382 7351  
Western Australia



## APPENDIX 27

Baseline data collection form

### BASELINE DATA

#### PATIENT (STICKER)

Telephone: (H): \_\_\_\_\_ (W): \_\_\_\_\_

#### CAREGIVER DETAILS:

Name: \_\_\_\_\_

Relationship to patient (circle):    Spouse    Daughter    Son    Sister    Brother  
Other

Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone: (H): \_\_\_\_\_ (W): \_\_\_\_\_

Birthdate: \_\_\_\_\_ (Age: \_\_\_\_\_)

#### GP DETAILS:

Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

#### CHECKLIST FOR BASELINE DATA COLLECTION :

##### PATIENT: CONSENT

BARTHEL (RA)

EQ5D (RA)

BERG (Physio)

HAD (RA)

CMM – SHOULDER (Physio)

CMM – POSTURAL (Physio)

DIARY

DISTRIBUTED

10 m WALK (Physio)

DIARY AND COPIES OF CONSENT AND PT INFO SHEET IN  
HEADSHEET; DESTINATION WARD RUNG/ EMAILED

DOB: \_\_\_\_\_ Age: \_\_\_\_\_

Gender (circle): M F

Date of Stroke: \_\_\_\_\_

Date of Referral: \_\_\_\_\_

Date of Transfer: \_\_\_\_\_

Transferred to (circle): RPH-SPC MH SKHS BHS

Living Arrangements Pre-Stroke(circle): Alone With Partner/ relative/ others

Function Pre-Stroke (circle): Independent Dependent

Stroke Site (circle): Left Right Brainstem/ Cerebellar

Stroke Pathology (circle): Ischaemic Haemorrhagic

Stroke Type (circle): TACS PACS LACS POCS

Clinical Symptoms on admission:

Abnormal language

Abnormal speech

Abnormal Swallow

Visual field loss or diplopia

Vertigo

Sensory changes of arm/leg

Weakness of arm/leg

Ataxia

Incontinence

Facial muscle weakness

Other (please detail) \_\_\_\_\_

Other (please detail) \_\_\_\_\_



Relevant Scores since admission (please date in brackets on left):

(      ) Scandinavian Stroke Scale Score      / 48

(      ) Glasgow Coma Scale Score                      E    / 3                      V    / 5    M    / 7

(      ) MMSE Score    / 30

(      ) Rankin              (0 – 6)                      \_\_\_\_\_

Smoking History (tick if applicable):                      Non-smoker

Current smoker

Past smoker

Medical History (tick if applicable):

Previous Stroke

Previous TIA

Previous SDH

Myocardial Infarction

Diabetes

Hypertension

Peripheral Vascular Disease

Ischaemic Heart Disease

Atrial Fibrillation

Hypercholesterolaemia (>6.5)

CABG or angioplasty

Endartectomy or angioplasty

Depression

Behavioural problems

Dementia

Pysch problems other than dementia



Alcohol Abuse

Other (please detail)



## APPENDIX 28

### Ethics approval letters

|   |  |   |
|---|--|---|
|  | <b>Department of Health</b><br>Government of Western Australia<br>East Metropolitan Health Service | <b>Royal Perth Hospital</b><br><small>ABN 13 993 250 709</small><br> |
|---|--|---|

**ETHICS COMMITTEE**


|  |   |
|--|---|
| <b>Clin Prof J A Millar PhD FRCP FRACP</b><br>Dept of Internal Medicine <i>Chairman</i><br>Tel: 9224 2461 Fax: 9224 2346<br>Email <a href="mailto:alasdair.millar@health.wa.gov.au">alasdair.millar@health.wa.gov.au</a> | Room 3105 Kirkman House<br>Tel: 9224 2292 |
|--|---|

|   |                  |
|---|------------------|
| <b>Ref: EC 2003/022</b><br><i>(This reference should be quoted on all correspondence)</i> | 21 November 2002 |
|---|------------------|


Dr G Hankey  
Head of Department  
Stroke Unit  
Royal Perth Hospital

Dear Dr Hankey 

**EC 2003/022 – Outcomes of different rehabilitation approaches in patients post-stroke: a randomised, controlled trial.**

Thank you for your letter dated 12 November 2002. The amendments to the above protocol are **APPROVED** by Chairman's prerogative.

Yours sincerely



J A Millar  
Chairman, Royal Perth Hospital Ethics Committee

(The Royal Perth Ethics Committee is constituted and operates in accordance with NH & MRC Guidelines. An Annual Report on the progress of your trial will be required (see Committee explanatory notes, available on Service)

|   |  |  |
|---|--|--|
| <b>Wellington Street Campus</b><br><small>Box X2213 GPO, Perth 6847<br/>Western Australia</small> | <b>Telephone: (08) 9224 2244</b><br><small>Facsimile: (08) 9224 3511<br/>T.T.Y. Line: (08) 9224 7016</small> | <b>Shenton Park Campus</b><br><small>6 Selby Street, Shenton Park 6008<br/>Western Australia</small> |
|   | <b>Telephone: (08) 9382 7171</b><br><small>Facsimile: (08) 9382 7351</small>                                 |  |

# MINUTE

# Curtin

UNIVERSITY OF TECHNOLOGY

|                |   |
|----------------|---|
| <b>To</b>      | Diane Dennis, Physiotherapy   |
| <b>From</b>    | Max Page, Executive Officer, Human Research Ethics Committee                            |
| <b>Subject</b> | Protocol Approval HR 192/2002   |
| <b>Date</b>    | 6 October 2002  |
| <b>Copy</b>    | Dr Kathy Briffa, Physiotherapy<br>Graduate Studies Officer, Division of Health Sciences |

Office of Research and Development

## Human Research Ethics Committee

TELEPHONE 9266 2784

FACSIMILE 9266 3793

EMAIL t.lerch@curtin.edu.au

On behalf of the Human Research Ethics Committee I am authorised to inform you that the project "OUTCOMES OF DIFFERENT REHABILITATION APPROACHES IN PATIENTS POST-STROKE: A RANDOMISED CONTROLLED TRIAL" is granted **provisional approval**, subject to further information/clarification of the points raised below. Please forward your response to the Secretary, HREC, C/- Office of Research & Development as soon as possible.

1. The client consent has been adequately addressed, however the therapist consent appears to have been overlooked. The information sheet implies that staff must participate. Please advise how therapist/staff consent will be obtained.

In addition to the above, one of the reviewers has queried the design of the study in which the authors are recruiting for a study to prove the null hypothesis (ie to show no difference). The reviewer has recommended that a statistician be consulted regarding the design and power of the study.

Final approval will be subject to a satisfactory response to the items above. Provisional approval of this project is for a period of twelve months 2/10/2002 to 1/10/2003.

When the project has finished or if at any time during the twelve months changes/amendments occur, or if a serious or unexpected adverse event occurs, the attached FORM B is to be completed and returned to Ms Tania Lerch, (Secretary, HREC) C/- Office of Research & Development as soon as possible. The approval number for your project is **HR 192/2002**. Please quote this number in any future correspondence.

Please find attached your protocol details together with the application form/cover sheet.

*Tania Lerch*

Maxwell Page  
Executive Officer  
Human Research Ethics Committee

J:\OR\HREC\REG99\HR 192/2002

Please Note: If information about the authorisation of this project is required, the following standard statement is suggested for inclusion in the information to subjects section of the protocol. *This study has been approved by the Curtin University Human Research Ethics Committee. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784.*

memorandum

|         |  |
|---------|--|
| To      | Diane Dennis, Physiotherapy  |
| From    | Dr Stephan Millett, Executive Officer, Human Research Ethics Committee |
| Subject | PROTOCOL APPROVAL –<br>EXTENSION HR 192/2002                           |
| Date    | 27 October 2005  |
| Copy    | Dr Kathy Briffa, Physiotherapy   |

Office of Research and Development

Human Research Ethics  
Committee

TELEPHONE 9266 2784  
FACSIMILE 9266 3793  
EMAIL [s.darley@curtin.edu.au](mailto:s.darley@curtin.edu.au)


The Human Research Ethics Committee acknowledges receipt of your Form B progress report for the project *Outcomes of different rehabilitation approaches in patients post-stroke: a randomised controlled study*.

Approval for this project is extended for the year to 1/10/2006.

Your approval number remains **HR 192/2002**. Please quote this number in any further correspondence regarding this project.

Thank you.



 Dr Stephan Millett  
Executive Officer  
Human Research Ethics Committee



## ETHICS COMMITTEE

Dear Ms Dennis,

The Bentley Health Service Ethics Committee, at its meeting of 11<sup>th</sup> of November, considered the proposal :-

**REF. NO: 6/02: Outcomes of Different Rehabilitation Approaches in Patients  
with Post-stroke: A Randomised Controlled Trial**

As raised with you during our phone conversation after the meeting there were two issues that I would like you to respond to in a note attached to your returned Letter of Agreement.

- Please articulate what provisions exist to ensure that patients with cognitive or communication problems are able to give (or withhold) their informed consent to their inclusion in the study?
- How is it communicated to the patients that their information (used for the research) is kept confidential?

It was the Committee's opinion that there were no other ethical objections to the project being undertaken.

Once we have received your signed Letter of Agreement, and note, you are free to proceed with the study.

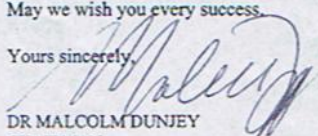
The procedures outlined in the proposal must be adhered to.

The NH & MRC Statement on Human Experimentation "Supplementary Note 1" states that Institutional Ethics Committees must provide surveillance of projects until completion of the protocol.

In accordance with these guidelines and those contained in the Letter of Agreement a progress report is to be submitted each twelve months until the research is completed.

May we wish you every success.

Yours sincerely,



DR MALCOLM DUNJEY  
CHAIRMAN  
ETHICS COMMITTEE  
BENTLEY HEALTH SERVICE  
19<sup>th</sup> November 2002

Review for your records.

**ETHICS COMMITTEE**  
**LETTER OF AGREEMENT**

**INVESTIGATOR** : Ms Diane Dennis

**TITLE OF STUDY** : Outcomes of Different Rehabilitation Approaches in Patients  
with Post-stroke: A Randomised Controlled Trial

**REF. NO.** : 6/02

The Bentley Health Service Ethics Committee has recommended the approval of your proposed study. When your signed original of this "Letter of Agreement" is lodged with the Convenor you may proceed with your research activities.

The following guidelines are provided for you to note prior to undertaking your study.

You should:

1. Notify, by letter, the Chairperson and appropriate others of the commencement date of the study.
2. Notify the Chairperson if any problems are being experienced during the implementation and process of the research activity.
3. Submit reports to the Ethics Committee at 12 months intervals and on completion of the study.
4. Notify the Convenor of any change of contact details to ensure that we are able to contact you.
5. Provide the Ethics Committee with a copy of the publication related to the research if/when it is published.
6. Follow any specific criteria or instructions from the Ethics Committee during the research activity.
7. Immediately notify the Chair or the Convenor of any Adverse Events.

DR MALCOLM DUNN

CHAIRMAN.....

DATE.....

CHIEF INVESTIGATOR.....

DATE 07012003



MERCY HOSPITAL  
MOUNT LAWLEY

Our Ref: MC/ad

Telephone: (08) 9370-9290 Nursing Administration  
Email: annetted@mercymt.com.au

Thirlmere Road  
Mount Lawley WA 6050

Tel 08 9370 9222  
Fax 08 9272 1229  
Email email@mercymt.com.au

December 24 2002

Ms Diane Dennis  
22 Dundas Road  
INGLEWOOD WA 6052

Dear Ms Dennis

**Re: OUTCOMES OF DIFFERENCE REHABILITATION APPROACHES IN PATIENTS  
POST STROKE: RANDOMISED CONTROLLED TRIAL**

Thank you for your recent letter which we received on December 5, 2002.

At our most recent Ethics Committee Meeting, your submission was discussed and I am pleased to inform you that approval has been granted to proceed with the above project.

We wish you well with your research.

Yours sincerely

**Maureen Colgan  
CHAIRPERSON  
ETHICS COMMITTEE  
MERCY HOSPITAL MOUNT LAWLEY**

*bringing compassion to life*  
*a member of the MercyCare group*  
Mercy Hospital Mount Lawley Inc ABN 29789126439





**Department of Health**  
Government of Western Australia  
East Metropolitan Health Service



**EXECUTIVE OFFICE**

☎ 9347 5400  
FAX: 9347 5410

(File Ref: 7.23)

11<sup>th</sup> December 2002

Ms Diane Dennis  
22 Dundas Road  
INGLEWOOD WA 6052

Dear Ms Dennis

Your letter was received on the 05<sup>th</sup> December 2002 concerning the proposed study on "Outcomes of different rehabilitation approaches in patients post-stroke".

Approval is now granted for patients under the care of the Swan Health Service Geriatricians to be involved in this randomised controlled trial.

Kind regards.

Yours sincerely

Garry England  
**A/GENERAL MANAGER**  
**SWAN AND KALAMUNDA HEALTH SERVICE**

Cc: Dr P K Loh

ES/21211GE3/C

Swan Health Service  
Eveline Road Middle Swan Western Australia 6056  
Letters PO Box 195 Midland Western Australia 6936  
Telephone (08) 9347 5244 (All Hours) Fax (08) 9347 5255  
ABN 13 993 250 709