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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

THE EFFECT OF SHOULDER STABILITY TRAINING ON UPPER LIMB FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH HEMIPLEGIA

Helena Nel (née van Wyk)

Johannesburg, 2016

A dissertation submitted to the Faculty of Health Sciences,
University of the Witwatersrand,
in fulfilment of the requirements for the degree of
Master of Science in Physiotherapy

Declaration

I, Helena Nel (née van Wyk), declare that this dissertation is my own work. It is being submitted for the degree of Master of Science (Physiotherapy) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

……

Signature

Signed on this …… day of …… 2016.

Witness:

……

Signature

Signed on this …… day of …… 2016.

Abstract

INTRODUCTION

Stroke is a major cause of mortality and long-term adult disability and has a significant physical and psychosocial impact on individuals and their Health-Related Quality of Life (HRQoL). The loss of upper limb function post-stroke directly impacts on shoulder girdle stability of the affected side. Shoulder girdle stability is essential for optimal functioning of the upper limb; good shoulder function is a prerequisite for effective hand function and the execution of the expected tasks with regard to activities of daily living (ADL). It is well known that the rehabilitation of the upper limb post-stroke remains challenging.

AIM

The aim of the study was to determine the effect of shoulder stability training using the Biodex Balance System (BBS) on shoulder girdle stability, upper-limb function, pain control and HRQoL in patients with hemiplegia post-stroke.

METHODS

The study utilised a quantitative longitudinal randomised control trial design with single blinding. Participants who met the inclusion criteria and who gave informed consent were assigned to one of two groups, the experimental or the control group, using computer-generated random numbers with concealed allocation. Participants were included in the study if they met the following criteria: were either male or female patients, who had a stroke, resulting in hemiplegia and/or shoulder instability, and were between the ages of 18 and 85 years. In addition to usual care, shoulder girdle stability training using the BBS was given to the participants in the experimental group. Assessments were done at baseline and one, three and six month's post-baseline.

All the participants were assessed by the research assistant using the following: pain measured by the Wong-Baker FACES Pain Rating Scale, the functionality of the upper limb measured by the Fugl-Meyer Assessment Upper Extremity, the shoulder

girdle stability measured by the Postural Stability Test on the BBS and HRQoL measured by the SF-36v2 Health Survey.

RESULTS AND DISCUSSION

A total of 17 participants were included in the main study after screening and, 53% were males. The median age of the study sample was 53 years. The control group comprised more female (n=5) than male (n=2) participants, while the experimental group comprised more male (n=7) than female (n=3) participants. All the participants in the control group were right-handed implying that more of them had their dominant hand affected than those in the experimental group. At baseline the two groups were comparable with regard to shoulder girdle stability, upper limb function and the HRQoL, but were not comparable regarding pain, as the control group experienced significantly more pain than the experimental group.

There were no statistically significant differences between the two groups with regard to shoulder girdle stability on any of the three BBS stability levels neither at the baseline (p=0.69) nor at one-month follow-up post-baseline (p=0.77).

There was no significant difference in upper limb function (baseline p=0.5, one month follow-up post-baseline p=0.93) between the control and the experimental groups for the entire study period. The severity of the impairment of upper limb function for both the control and the experimental group was comparable at baseline and improved from moderate (56-79) to mild (>79) during the duration of the study.

At baseline the participants in the control group already expierienced more pain than the experimental group (p=0.05). Participants in the control group experienced significantly more shoulder pain than the experimental group at the one-month follow-up (p=0.02), but no differences were found at the three- (p=0.17) and six-months(p=0.12) follow-up post-baseline.

At baseline a statistically significant difference was found regarding the impact of emotional problems on role limitation (p = 0.03) and pain (p = 0.05) between the two groups, with the control group indicating lower scores than the experimental group. At

one month a statistically significant difference was found between the two groups regarding the extent of impaired social functioning (p = 0.05).

The participants in the experimental group reported improvement in their health over time (baseline = 67.5 and six-month follow-up post baseline = 86.11). None of the factors investigated in this study impacted on HRQoL outcomes over time.

CONCLUSION

Shoulder girdle stability training using the BBS did not result in significant improvements in shoulder girdle stability, upper limb function, pain relief and HRQoL post-stroke in this cohort. The findings in this study could have been influenced by the small sample size (the power calculation was done only for the shoulder girdle stability) and also by participants in the control and experimental group continuing with their standard care, which included an intensive rehabilitation programme. This could have been a confounding factor impacting on the outcome. Further research in this field is required.

KEY WORDS

Shoulder stability training, Biodex Balance System SD, Hemiplegia post-stroke, Upper limb function, Upper limb pain, Health-Related Quality of Life (HRQoL), Factors associated with shoulder girdle stability.

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List of abbreviations and acronyms

ADL	Activities of daily living
CVA	Cerebral vascular accident
DALY	Disability-adjusted life years
FES	Functional electrical stimulation
FIM	Functional independence measure
FMA-UE	Fugl-Meyer Assessment Upper Extremity
HRQoL	Health-related quality of life
PST	Postural Stability Test
ROM	Range of motion
SASPI	Southern African Stroke Prevention Initiative
SF-36	Short-Form 36 Questionnaire
SI	Stability Index
SIS	Stroke Impact Scale
WBFPRS	Wong-Baker Faces Pain Rating Scale
WHO	World Health Organisation

Definitions

Cognitive impairment for the purpose of the study, is indicated by a mean FIM score of less than three (out of seven) for the cognitive group as documented in the screening information and/or a screening score of less than 15 (out of 30) for the mini-mental cognitive screening tool.

DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost due to premature mortality in the population and the Years Lost due to Disability for people living with the disease or health condition or its consequences (WHO, 2013).

Health change (SF-36v2) is the self-perception of an individual's health and indicates the overall health status and is associated with changes in functioning (Atif et al., 2013).

Postural or core stability "has been defined as the ability to control the body's COM within a given base of support" (Shumway-Cook & Woollacot, 2012).

Visual impairment for the purpose of the study is indicated by an inability to read words in a font size of Arial 12, with or without spectacles.

CHAPTER 1

1. INTRODUCTION AND BACKGROUND TO THE STUDY

1.1 Background and need

A cerebral vascular accident (CVA), also referred to as a stroke, is a major cause of mortality and long-term adult disability (Takeuchi & Izumi, 2013). Annually 15 million people experience strokes worldwide and it is one of the top ten causes of disability (Feigin et al., 2014; Kim & Johnston, 2011; Roger et al., 2011). In South Africa stroke is one of the leading four causes of death in adults (Feigin et al., 2014; Kim & Johnston, 2011; Roger et al., 2011).

Post-stroke patients may present with impairment of mental status, perception, sensation, communication and/or motor ability on the contra-lateral side of the body (Takeuchi & Izumi, 2013). After a stroke, 85% of survivors present with an initial motor and/or sensory deficit of the upper limb. Improvement in upper- limb function is poor in most cases. In 55% – 75% of cases, the person still presents with poor upper-limb function three to six months after the initial incident (Harris et al., 2010; Kwakkel et al., 2006).

Effective neurological rehabilitation is central to the recovery of stroke survivors and has a significant impact on the HRQoL (Lang et al., 2012; Smith, 2012). Stroke-related disability can greatly impact on a person's HRQoL and the ability to live independently (Lang et al., 2012; Smith, 2012). Key factors associated with HRQoL could be stroke-specific symptoms as stated above, or other factors such as social support, demographics, depression, dependency in activities of daily living (ADL) and pre-existing co-morbidities that may also impact on the HRQoL (Morris et al., 2013; De Weerd et al., 2012; Kissela, 2006).

Various factors may influence the recovery process of the upper limb after stroke. About three quarters (75%) of strokes occur in the region of the brain supplied by the

middle cerebral artery, therefore affecting upper-limb function (Pattern et al., 2006). The upper and lower limbs differ with regard to the extent of cortical representation and spasticity (which occur more frequently in the upper limb) (Pattern et al., 2006). Post-stroke there is a tendency in stroke survivors only to make use of the unaffected limb during functional activities (Takeuchi & Izumi, 2013). This is due to the motor and/or sensory loss, abnormal tone of the upper limb and complications that may arise post-stroke (Morris et al., 2013; Lang et al., 2012). These complications may lead to decreased shoulder and shoulder girdle stability which is required for optimal functioning of the upper limb (Lang et al., 2012; Davies, 2000). The absence and the prevention of these complications will improve the patient's participation and functional outcomes post-stroke (Lang et al., 2012; Davies, 2000), and is a positive indicator relating to health-related quality of life (HRQoL) (Smith, 2012).

Post-stroke, most of the survivors do regain mobility, but the functional use of the affected upper limb does not return (Morris et al., 2013; Lang et al., 2012). The rehabilitation of the hemiplegic upper limb remains a challenge, although many therapeutic modalities and approaches are available. The lack of positive findings regarding the outcomes after stroke rehabilitation in the literature may be due to various reasons, including the low statistical power of the studies, the heterogeneity of study populations and the limited response of outcomes measures (Lang et al., 2012; Pattern et al., 2006).

During neurological rehabilitation emphasis is placed on task-specific and functional modalities that focus on ADL (Pattern et al., 2006). These processes improve motor learning and promote neural plasticity which enhances the recovery of function at a behavioural level (Pattern et al., 2006) and ultimately the HRQoL. Treatment principles should include the prevention of biomechanical changes, decreasing of muscle and joint stiffness, reduction of spasticity and the re-education and facilitation of function (Brewer et al., 2012). Various treatment modalities are available for the re-learning of the upper-limb function such as task-oriented training, passive movements, compensatory training, bilateral upper-limb training, rhythmical auditory cueing combined with repetitive reaching, constraint-induced therapy, sensorimotor stimulation, weight-bearing and dynamic, high-intensity resistance training, as well as

mirror therapy (Brewer et al., 2012; Stoykov et al., 2009; Pattern et al., 2006). Weight bearing (closed chain exercises) may be used to activate muscle activity especially when the stroke survivor has poor activity due to neglect or dyspraxia (Lang et al., 2012; Davies, 2000). Efficacy of task-specific training can be determined by the intensity and task specificity; studies also indicated upper-limb movement (Thielman & Bonsall, 2012; Kwakkel et al., 2008; Kwakkel et al., 2006). Bilateral arm training with rhythmic auditory cueing (BATRAC), as well as unilateral training, for example, constrained-induced movement therapy (CIMT) has been shown to improve upper-limb function (Page et al., 2008; Wu et al., 2007; Wolf et al., 2006; Luft et al., 2004). Mirror therapy is non-invasive brain stimulation and makes use of visually-guided upper-limb movements and research indicated positive effects (Brunoni et al., 2012).

The Biodex Balance System (BBS) is a recent modality introduced in neurological rehabilitation (Cachupe et al., 2001). The BBS is an objective measuring tool of an individual's ability to stabilise the involved joint (Karimi et al., 2008). BBS programmes are used for the restoration of the affected motor skills by retraining new neural pathways, proprioception and the maintenance of positioning, balance and weight transfer. The BBS is effective because it provides immediate feedback and allows the patient to repeat the movements more correctly. It also documents treatment session results and assists in monitoring data objectively (Cachupe et al., 2001).

Limited research has been done on the BBS specifically with regard to its effect on the rehabilitation of the upper limb post-stroke. The BBS has been used mostly for balance training in a standing position. This study, therefore, aimed to address this gap in the literature on neurological rehabilitation by determining the effect of the BBS on the hemiplegic upper limb and ultimately the HRQoL of stroke survivors.

1.2 Problem statement

The loss of the use of an upper limb is one of the most frequent and devastating consequences of stroke. Despite intensive rehabilitation efforts of the upper limb the

prognosis remains poor in most cases (Brewer et al., 2012). Post-stroke disability may have a great impact on patients' HRQoL and the ability to take care of themselves, therefore effective neurological rehabilitation is important for the improvement of these patients' condition (Brewer et al., 2012).

The upper limb plays a key role in the performance of functional activities (bilateral and unilateral) and in determining the HRQoL of the individual (Takeuchi & Izumi, 2013). Patients also may be more dependent on care and/or assistance for basic ADL post-stroke resulting in the loss of upper limb function (Rhoda et al., 2015).

Although evidence is widely available on the efficacy of the BBS on patients in general and on patient outcomes post-stroke with regard to balance and gait retraining, there is a dearth of literature on its effect on the hemiplegic upper limb (Pereira et al., 2008; Aydoğ et al., 2006; Ballard, 2005; Baldwin et al., 2004).

Although various treatment techniques have been researched, the upper-limb outcomes post-stroke generally remain poor with regard to function and pain relief (Thielman & Bonsall, 2012; Kwakkel et al., 2008; Page et al., 2008; Wu et al., 2007; Wolf et al., 2006; Luft et al., 2004). Poor upper-limb function also affects the HRQoL of a patient (Richards et al., 2008; Waller & Whitall, 2005). The effect of the upper-limb weight-bearing training on the BBS on these outcomes post-stroke is largely unknown. The outcome of more research in combination with information about upper-limb recovery will assist clinicians to make appropriate decisions when selecting evidence-based therapies for the affected upper limb.

Limited studies have been conducted in this field using the BBS to assess and train shoulder girdle in patients post-stroke. This study used the same principles (see Section 2.7.3) as those used for lower-limb balance assessment and training on the upper limb in the post-stroke population.

1.3 Research question

The research question for the study was:

- What is the effect of shoulder stability training (using the BBS) on shoulder girdle stability, upper limb function, pain control/relief and HRQoL in hemiplegic patients post-stroke?

1.4 Aim of the study

The aim of the study was to determine the effect that shoulder stability training by means of the BBS has on shoulder girdle stability, upper limb function, pain control/relief and HRQoL in patients with hemiplegia post-stroke.

1.4.1 Objectives of the study

In order to be able to achieve the aim of the study, objectives were set with great care.

The primary objective of the study was

- to establish the effect of shoulder stability training using the BBS on shoulder girdle stability at baseline and one month post-baseline in patients with hemiplegia post-stroke.

The secondary objectives of the study were to establish:

- the effect of shoulder stability training using the BBS on upper limb function at baseline and one month post-baseline in patients with hemiplegia post-stroke,
- the effect of shoulder stability training using the BBS on upper limb pain at baseline, one, three and six months post-baseline in patients with hemiplegia post-stroke,
- the effect of shoulder stability training using the BBS on the HRQoL at baseline, one, three and six months post-baseline in patients with hemiplegia post-stroke, and

- the factors associated with shoulder girdle stability in patients with hemiplegia post-stroke.

1.5 Significance of research

Spontaneous recovery post-stroke is limited, and stroke survivors will continue to experience decreased functioning of the upper limb as well as HRQoL (Kwakkel et al., 2006). The execution of normal ADL requires about 54% bilateral upper-limb use (van Delden et al., 2009).

In this study, the upper-limb weight-bearing training did not positively influence upper-limb function or pain in this group of patients. Both groups indicated improved HRQoL but no functional benefits outcomes over time. The rehabilitation of the upper limb post-stroke remains challenging.

Although this study did not indicate significant evidence the researcher suggests further research in this field applying the same general principles such as bilateral tasks, weight bearing, and visual, tactile, or verbal cues to encourage participants to focus on upper-limb activation and function on the BBS. The development of upper-limb weight-bearing treatment programmes for use on the BBS applying these principles may also assist in reducing and/or preventing pain, as well as preventing other co-morbidities of the upper limb post-stroke. Ultimately this might lead to improvement in the upper-limb function as well as the HRQoL of patients post-stroke.

1.6 Outline of the research report

This research study will be reported on in the remainder of this dissertation following the outline below.

Chapter 2: Literature review

Chapter 2 is devoted on reporting on an in-depth literature review discussing and describing the literature relevant to the objectives and aim of the study. It focuses on a broad outline of hemiplegia caused by a stroke, followed by in-depth discussions of normal upper limb function and shoulder girdle stability, the prevalence of upper limb involvement and associated pain after stroke, followed by the influence of upper-limb

function on HRQoL after stroke and the rehabilitation principles for improving and restoring shoulder girdle stability and upper-limb function. Lastly it include a description of the instruments, including the BBS, and outcome measures used during the study.

Chapter 3: Research methodology

Chapter 3 entails a description of the research methodology applied in the study. This includes aspects such as the study design, variables, hypothesis testing and the sample selected. Furthermore, it gives a detailed description of the data collection and the methods applied for data analysis. The ethical considerations and possible methodological errors related to the study are also being presented.

Chapter 4: Results

In Chapter 4 the most important results are summarised using tables and paragraphs amongst others. The inclusion procedure and reasons for exclusion are also explained. Lack of follow-up that occurred during the study is described and reasons for drop-out also outlined.

Chapter 5: Discussion

Chapter 5 compromises an in-depth discussion on the findings of the study in the context of the available literature, and possible reasons for the findings are provided.

Chapter 6: Conclusion, limitations and recommendations

Chapter 6 provides the conclusions, limitations and recommendations for future research and implementation in clinical practice.

1.7 Conclusion

This chapter gave a brief overview of the study, focusing on the main theoretical and methodological aspects underlying this study. The next chapter consists of an in-depth discussion of the literature, including aspects such as the effects of shoulder stability training on upper-limb function, the HRQoL in patients post-stroke, and the use of the BBS and other outcomes measures in neurological rehabilitation.

CHAPTER 2

2. LITERATURE REVIEW

2.1 Introduction

This chapter reports on an in-depth literature review discussing and describing the literature relevant to the objectives and aim of the study. The search engines used to obtain sources for the literature review were the Cochrane Database, PubMed, Google Scholar and the Pedro Database. The literature included dates from 1998 to 2015. The key words used in the literature searches were as follows: Hemiplegia, stroke, prevalence, upper-limb function, shoulder-girdle stability, risk factors, pain post-stroke, HRQoL, rehabilitation, Biodex Balance System (BBS), outcome measures.

In order to clearly understand the aim and objectives of this study, this chapter firstly focuses on a broad outline of hemiplegia caused by a stroke, followed by in-depth discussions of normal upper-limb function and shoulder-girdle stability. Then the prevalence of upper-limb involvement and associated pain after stroke is discussed, followed by the influence of upper-limb function on HRQoL after stroke and the rehabilitation principles for improving and restoring shoulder-girdle stability and upper-limb function. The last section contains a description of the instruments, including the BBS, and outcome measures used during the study.

2.2 Background information on stroke

A cerebral vascular accident (CVA), also referred to as a stroke, is one of the major causes of mortality and long-term adult disability and affects the cognitive, social, emotional, communication and physical functioning of the person (Takeuchi & Izumi, 2013). The World Health Organisation (WHO) (2006: 151) defines a stroke as a

"*clinical syndrome with rapidly developing signs of focal or global disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than vascular origin*".

Worldwide 15 million people are affected by stroke annually, of which one-third die and one-third are left permanently disabled. Stroke is one of the top ten causes of disability worldwide (Feigin et al., 2014; Mudzi et al., 2012; Kim & Johnston, 2011; Roger et al., 2011). A study done in South Africa by Bertram et al. (2013) established that the annual estimation of stroke was 75 000 and the burden of disease was 564 000 disability-adjusted life years (DALYs). Stroke causes an increasing problem regarding disability due to the high incidence as well as the severity in South Africa and sub-Saharan Africa and leaves between 64% and 66% of survivors with some level of disability (Damasceno et al., 2010; SASPI Project Team, 2004). In developed countries stroke is considered the third most common cause of death (one in every 10 deaths), exceeded only by coronary heart disease and cancer. In South Africa stroke is one of the leading four causes of death (Feigin et al., 2014; Kalichman & Ratmansky, 2011; Kim & Johnston, 2011; Roger et al., 2011).

A stroke may be caused by ischemia due to a thrombus, embolism or haemorrhage (Lang et al., 2012; Davies, 2000) and there may be various underlying risk factors (Afridi et al., 2015; Foerch et al., 2013). A number of stroke risk factors are not modifiable such as age, gender and family history. Other risk factors may be reduced through lifestyle measures, medications and/or surgery (Afridi et al., 2015; Foerch et al., 2013; Khan et al., 2009). These risk factors include: hypertension, heart disease, hyperlipidaemia, atrial fibrillation, diabetes mellitus, smoking, obesity, alcohol consumption and reduced physical activity.

2.2.1 Risk factors of stroke

The average age of patients experiencing stroke is between the ages of 70 and 79 years with 70 years being the average age in males and 75 years the average age in females (De Weerd et al., 2012; Mohammad et al., 2012). Strokes occur mostly in

individuals older than 45 years and according to the WHO (2013), it is the second leading cause of death of people above the age of 60 years and the fifth leading cause of death in people aged 15 to 59 years (Feigin et al., 2014; Kalichman & Ratmansky, 2011; Kim & Johnston, 2011; Roger et al., 2011). After age 55, the risk of a stroke doubles with each decade (Afridi et al., 2015). Males and females present with similar conventional risk factors for stroke; hypertension and atrial fibrillation are more prevalent in females whereas smoking, alcohol consumption, coronary artery disease and diabetes are higher in males (Reeves et al., 2008). Various studies indicated contradictory findings with regard to gender- specific prevalence (Afridi et al., 2015; Boutayeb et al., 2014; Yao et al., 2012). Females tend to be more disabled than men post-stroke; this might be due the fact that females are older when they have a stroke (Afridi et al., 2015; Reeves et al., 2008).

Hypertension is considered the commonest risk factor and plays a role in about 70% of ischemic and haemorrhagic strokes (Afridi et al., 2015). Heart disease and atrial fibrillation may also increase the risk of stroke (Roger et al., 2011). Diabetes is another significant contributor to stroke and also has an influence on atherosclerosis, hypertension, obesity and hyperlipidaemia (Afridi et al., 2015; Kamouchi et al., 2011). A long duration of diabetes may also increase the risk of stroke and females are also at greater risk than males (Khan et al., 2009). Serum cholesterol contributes to atherosclerosis and is a risk factor for ischemic strokes as well as for coronary heart disease (Afridi et al., 2015; Varbo et al., 2011).

Specific lifestyles for example smoking, obesity, alcohol consumption and reduced physical activity have demonstrated a relationship with the increased risk of stroke (Afridi et al., 2015). Regular physical activity indicated a lower risk of stroke; most likely by reducing other stroke risk factors such as obesity and hypertension. Research also indicated that inactivity may increase the risk of stroke with 33 % (Afridi et al., 2015). Obesity increases the risk of stroke by 50 to 100 %, but may be managed by a healthy diet that may influence a number of other stroke risk factors including hypertension, hyperlipidaemia and diabetes. Females were found to have a higher rate of obesity (24.2%) than males (3.5%) (Afridi et al., 2015; Ejim et al., 2011; Wahab et al., 2011). Smoking and alcohol consumption are other lifestyle

contributors to both ischemic and haemorrhagic strokes. In general, cigarette smokers have a two to three times higher risk of stroke than non-smokers, and the more cigarettes smoked, the greater the risk. More than two drinks a day on a regular basis can double the risk of stroke risk by producing abnormal heart rhythms, leading to hypertension and increasing blood clot formation (Afridi et al., 2015; Goldstein et al., 2011). Chronic stress and depression can also be associated with an increased risk of stroke, particularly ischemic stroke (Afridi et al., 2015).

Another rising risk factor for stroke is HIV/AIDS and the use of anti-retroviral medicines (Worm et al., 2010). There are many reasons why someone who is immunosuppressed with HIV may present with a stroke (e.g., as a result of tuberculous meningitis, toxoplasmosis affecting the cerebral blood vessels or even leading to cardiac disease) (Worm et al., 2010). HIV has been associated with coagulation abnormalities, such as Protein S deficiency (Worm et al., 2010).

2.2.2 Clinical presentation of stroke

The clinical presentation post-stroke is described making use of the anatomical regions of the brain affected. All the cerebral hemispheres, except the posterior hemispheres, are supplied by the carotid/anterior circulation and the brain stem while the posterior hemispheres are supplied by the vertebral basilar/posterior circulation (Lang et al., 2012; Davies, 2000). Each hemisphere has its own specialization, but normal and complex activities require the integrated function of both hemispheres. Post-stroke patients have diffuse cerebrovascular disease and other conditions resulting in impaired cerebral circulation. The clinical presentation can be complicated as there may be other areas of ischemic damage located throughout the hemispheres apart from the one major area of infarction (Lang et al., 2012; Davies, 2000). Post-stroke hemiparesis is the most common motor impairment and affects the opposite side of the body than the side affected in the brain (Lang et al., 2012).

Post-stroke the patient may present with various impairments. The right hemisphere is dominant for visuospatial orientation, constructional praxis and judgement in over 90% of the population, thus post-stroke visual-spatial perceptual disorders include

left-sided neglect disorientation, constructional apraxia and asterognosis (Takeuchi & Izumi, 2013; Kwasnica, 2002). Unilateral neglect syndrome forms part of visual-spatial perceptual disorders and is more common on the left side than on the right side. Possible reasons for this is that the right hemisphere regulates attention more than the left hemisphere, while the left hemisphere is responsible for modulating attention and arousal for the right visual field only; therefore, the right hemisphere is more able to compensate post-stroke for left hemisphere impairment. Another behavioural abnormality occurring with unilateral neglect is anosognosia, that is when the patients are unable to notice their opposite limbs and do not use the limb during functional activities (Takeuchi & Izumi, 2013; Demirci et al., 2007; Ratnasabapathy et al., 2003; Kwasnica, 2002). Although patients with right hemispheric lesions might not present with communication difficulties, they may tend to have a lack of insight into their own deficits and often are impulsive and emotionally labelled. These patients also may experience difficulty telling or understanding jokes as well as having more complex discussions which result in social dysfunction (Demirci et al., 2007; Ratnasabapathy et al., 2003; Kwasnica, 2002).

As the left hemisphere is responsible for learning and using language symbols, affliction in post-stroke patients may result in aphasia and apraxia (Brewer et al., 2012; Poslawsky et al., 2010). Aphasia is a language disorder and expressive (Broca's) aphasia is most commonly seen among post-stroke patients. Apraxia is a disorder of voluntary movement , resulting in post-stroke patients being unable to perform activities required despite optimal movement, muscle strength, sensation, co-ordination and comprehension (Brewer et al., 2012; Poslawsky et al., 2010).

Other complications not specific to the left or right hemisphere also include cognitive impairments when the patients present with decreased attention, executive function, and processing speed (De Weerd et al., 2012; Pattern et al., 2006). Other complaints post-stroke may be regarding consciousness (attention and/or alertness), fatigue, lack of motivation and mood (depression) and/or personality (Morris et al., 2013; Takeuchi & Izumi, 2013). Post-stroke patients often are unable to communicate their feelings due to aphasia. Function and depression interact with each other where a decrease in function may lead to depression and depression may lead to a decrease

in function (Morris et al., 2013). Patients may experience a change in how they perceive themselves post-stroke (self-image), which is also associated with depression and may lead to social withdrawal (Morris et al., 2013). Patients may also present with dysphagia, dysphonia and/or dysarthria and/or dysphasia. Dysphagia may lead to malnutrition and dehydration, which may influence the functional outcomes. Dysphagia is associated with aspiration that increases the risk of aspiration pneumonia (Gialanella et al., 2012; Meijer et al., 2003).

Motor impairments post-stroke patients experience may be reduced muscle strength and/or tone, increased tone, change in sensation and/or proprioception, decreased coordination, reduced joint stability and/or mobility, balance impairment and impaired gait (Takeuchi & Izumi, 2013). These symptoms and associated problems may change and/or fluctuate during the acute and chronic stages, and are dependent on the rehabilitation, care and the severity of the stroke. Symptoms may also affect patients' functional ability negatively and consequently their HRQoL (Morris et al., 2013; De Weerd et al., 2012).

Post-stroke, 80% of individuals present in varying degrees with motor impairment, which impacts the control of movement of the face, and upper and lower limb on one side of the body (Brewer et al., 2012). Therefore, the main focus of physiotherapy post-stroke should be on the restoration of impaired movement and function, and should aim to reduce the impairment and disability and to encourage participation in activities of daily living (ADL) (Brewer et al., 2012). Shoulder-girdle stability is important for optimal functioning of the upper limb, whilst good shoulder function is a prerequisite for effective hand function and the execution of the expected tasks with regard to ADL (Pollock et al., 2014; Brukner et al., 2012).

Having reviewed the possible impairments that may be caused by stroke, upper-limb functionality and postural stability were taken under scrutiny in the literature review.

2.3 Upper-limb function, shoulder-girdle stability and postural stability

The upper limb plays an important role in ADL because it serves as an individual's most functional extremity (Pollock et al., 2014; Brukner et al., 2012). In this study the importance of shoulder-girdle stability is emphasised because it constitutes the link between the trunk and the upper limb. Shoulder-girdle stability and postural stability are important for the ability to perform optimal upper-limb movement.

The hand and upper limb have many functions which include:

- communication, for example, expression and gesturing,
- execution of ADL, such as eating, grooming and dressing,
- protection, for example, maintaining balance and stability,
- enhancing body image: it forms part of body scheme and image, and
- thermoregulation: it plays a role in temperature regulation (Hunter & Chrome, 2002).

Functional tasks of the upper limb include grabbing, holding and manipulating objects in the hand and require complex integration of movement from the shoulder girdle down to the fingertips (Brewer et al., 2012). In order to move the hand during functional activities, dynamic stability of the proximal joints, including the upper limb, shoulder girdle and trunk, is of the utmost importance (Hunter & Chrome, 2002).

The shoulder and the shoulder girdle play an integral role in functional activities because they provide proximal stability to the upper limb by acting as a base of support for upper-limb movement (Brukner et al., 2012). Shoulder-girdle stability is essential for placement and reaching with the hand in front of the body as well as providing a stable base for the gleno-humeral muscles to move from (Brukner et al., 2012). A decrease in shoulder-girdle stability will influence the functioning of the upper limb negatively (Brukner et al., 2012). For improved upper-limb functioning post-stroke, normal functioning of the shoulder joint is important. Normal functioning of the shoulder joint is best understood when one has an understanding of the anatomy of the shoulder girdle.

2.3.1 Anatomy of the shoulder girdle and shoulder girdle stability

The shoulder is a complex joint, has the greatest mobility of all the joints in the human body and works as a complex mechanical system (Kalichman & Ratmansky, 2011; Garofalo et al., 2009). The shoulder girdle consists of four joints, namely the gleno-humeral, scapula-thoracic, sterno-clavicular and acromio-clavicular joints (see Figure 2.1). These joints all have functions as individual joints, but each joint also forms an important part of the single, complex shoulder-girdle system. Adequate range of motion (ROM) and muscle function are required for normal arm movements (Garofalo et al., 2009).

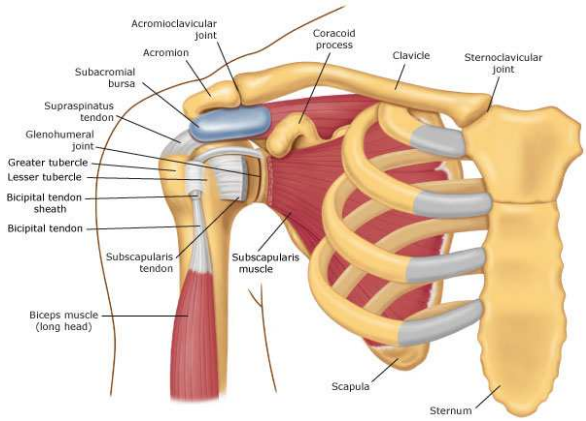


Figure 2.1: Shoulder girdle muscle and joints
(Copied from Spencer, 2009)

Due to the composition of the bony structures, ligaments and muscles of the shoulder girdle, the shoulder joint is very unstable. The shoulder girdle is the link between the trunk and the upper limb. Optimal stability of movement and the ability to position the scapula are essential to ensure accurate upper limb function (Brukner et al., 2012, Moore et al., 2010). As indicated by Shadmehr et al. (2010), shoulder stability consists of both static and dynamic factors. Dynamic and static stability of the shoulder not only protects the joint from the effects of gravity, but also prevents pain due to soft tissue damage (Smith, 2012). Dynamic stability of the shoulder girdle relies on the surrounding muscles because the Gleno-humeral joint is minimally constrained by articular anatomy (Roy et al., 2011). Static stability is provided by the bony structures and the joint capsule (Smith, 2012).

In order to maintain a stable shoulder joint, both mechanical and dynamic control mechanisms are needed, including neuromuscular control, proprioception, and sensation of force, joint position sense and kinaesthesia. These components form part of the sensorimotor system (Myers et al., 2006). Proprioception at the shoulder fulfils a significant function in shoulder-girdle stability through immediate contraction of the muscles against external forces (Smith, 2012). Mechanoreceptors located in the skin, muscle and joint tissue sense the joint position, weight bearing, direction, velocity of movement and pain, and trigger the contraction of the muscles against external forces as needed. Proprioception dysfunction is strongly associated with difficulties in postural control and ADL. In the upper limb it is the key to enabling natural motions in the absence of visual perception to perform ADL (Smith, 2012; Martin & Fish, 2008).

The literature indicates a difference in the stability of the shoulder joint of men and women due to muscular features (Anders et al., 2004). Men have a more precise and higher shoulder activation level than women, which provides more stability in men (Anders et al., 2004). Another factor accounting for this difference may be the anatomy of the glenoid fossa with regard to the size and shape in men – the glenoid fossa is bigger in men and provides more stability than in women (Merrill et al., 2009).

Shoulder instability is a general term referring to many different problems that may arise from various conditions affecting the shoulder. Three types of instability may occur, namely anterior, posterior and multi-directional instability.

a) Anterior instability is found in 95% of instability cases. It mostly follows after an acute anterior dislocation of the shoulder and causes an avulsion or stretching of the glenoid labrum and the capsule (Solomon et al., 2005).
b) Posterior instability often occurs after a posterior dislocation of the shoulder. It is less common than anterior instability and is often missed. Posterior instability occurs with repetitive trauma to shoulders. Shoulder pain often occurs when loading the flexed and internally rotated shoulder and may be confused with sub-acromial pain (Lewis et al., 2004).

c) Multi-directional instability results from anterior, posterior or inferior subluxation or dislocation of the gleno-humeral head (Solomon et al., 2005). This may be due to general ligamentous and capsular laxity in the body or due to recurrent trauma (Solomon et al., 2005).

Stroke may be considered a leading cause of shoulder instability (Brewer et al., 2012).

2.3.2 Postural stability

Postural stability is essential for performing ADL and may be divided into static stability and functional stability. Achieving optimal postural stability however remains complicated (Pickerill & Harter, 2011). Postural stability requires a complex interaction of the stabilisers of the spine (the muscles), structural stability (the vertebral column), neural control and other components such as joint ROM, trunk flexibility, muscle properties and biomechanical relationships among body segments that act together for the execution of ADL (Shumway-Cook & Woollacot, 2012; Okada et al., 2011). Muscles of the shoulder and pelvis should be included in postural stability, because they play an integral role in the transfer of forces across the body (Zazulak et al., 2007). Postural stability and strength also play a significant part in upper and lower extremity movement (Aytar et al., 2012). Findings by Aytar et al. (2012) indicated that reduced postural stability interrupts the transfer of energy, which may result in reduced ability to perform ADL effectively.

To maintain postural stability, the body must be able to integrate both sensory and motor processing and biomechanical strategies with learned responses to be able to anticipate postural changes. The trunk should be able to control and adapt during internal and external changes of the body, including movement of the distal extremities and balance challenges (Shumway-Cook & Woollacot, 2012). In addition, the ligaments and intervertebral discs that form part of the passive joint structures contribute to postural stability by providing joint stiffness. The active sub-system of trunk muscles contributes to stability through co-contraction (Gardner-Morse & Stokes, 2003; Van Dieën et al., 2003). The nervous system assists by controlling the

muscle activity that contributes to stability aided by a feedback system which consists of sensory (muscle and joint receptors), visual as well as vestibular input (Goodworth & Peterka, 2009; Moorhouse & Granata, 2007).

Thus, the neuromuscular system is vital in maintaining the core by activating muscles during activities. During fast upper- limb movements, muscle activation starts in the lower extremities and continues upwards through the trunk and to the upper limb (Zazulak et al., 2007). Shumway-Cook and Woollacot (2012) explain that functional activities need patterns of joint stability and mobility throughout the body.

Postural stability is a complex function required for the performance of most functional activities and is controlled by sensory input, central processing and neuromuscular responses. It is important to have an intact neuromuscular system and sufficient muscle strength to regain postural stability when it has been disturbed. Postural control is important in order to maintain the correct alignment and positioning, to remain stable during position changing, to execute ADL and maintain mobility (Aydoğ et al., 2006; Karatas et al., 2004).

If postural stability post-stroke is not regained, the patient is going to struggle with the execution of all the distal movement and ADL.

2.4 The prevalence of upper limb problems post-stroke

Problems with upper-limb function are common post-stroke due to damage to the primary motor cortex, the primary somatosensory cortex, secondary sensorimotor cortical areas, subcortical structures, and/or the corticospinal tracts (Lang et al., 2012). Stroke leads to varying degrees of weakness in the upper limb that result in ineffective, slower and inaccurate movements on the affected side when compared to those of healthy individuals (Lang et al., 2012; Smith, 2012).

According to the International Classification of Function and Disability (ICF), decreased upper-limb movement or sensation is considered impairment of body structure or function and may result in activity limitation, for example, dysfunction in

task performance and participation restriction, such as in eating or pouring water from a jug. It is important to distinguish between the two: impairment is concerned with movement and activity limitation with task performance, but the one will still influence the other (Morris et al., 2013; Lang et al., 2012).

Furthermore, impairments include difficulty in moving and coordinating the upper limb, and hand and fingers of the affected limb resulting in difficulty with ADL such as eating, dressing and washing (Lang et al., 2012). Post-stroke, even mild impairment of upper limb function may result in remarkable limitations in ADL and may have a negative impact on the HRQoL (Lang et al., 2012). Shoulder-girdle stability and postural stability are important for the ability to perform optimal upper-limb movement (Brukner et al., 2012). Stroke can be considered a cause of postural and shoulder instability (Brewer et al., 2012).

2.4.1 Postural stability post-stroke

Postural stability is an essential key component of balance and coordinated upper limb movement for ADL as well as the execution of difficult motor tasks and participation in sports (Lang et al., 2012; Aydoğ et al., 2006). Stroke may influence the functioning of trunk muscles bilaterally (Lang et al., 2012; Aydoğ et al., 2006). It is critical to maintain optimal postural control in stable and/or unstable positions during functional activities such as transfers, reaching activities and mobility (Aydoğ et al., 2006; Karatas et al., 2004). Following stroke, the stability of the shoulder frequently is compromised, increasing the risk of damage to the soft tissue structures of the shoulder and reducing the upper limb function (Smith, 2012; Aydoğ et al., 2006).

Post-stroke patients may experience limitation during reaching activities and use excessive trunk and/or shoulder girdle movement. This is an indication of increased recruitment and is a compensatory mechanism (Smith, 2012; Aydoğ et al., 2006).

2.4.2 Shoulder girdle stability post-stroke

Shoulder instability is usually found in 90% of patients affected by stroke (Smith, 2012). Initially after stroke, the limb is hypotonic (flaccid paralysis), and post-stroke after the first few weeks and/or months post-stroke hypertonicity develops. Hypo- and hypertonicity may lead to shoulder-girdle instability due to decreased mobility (Lang et al., 2012; Davies, 2000).

In 17–18% of patients affected by stroke, paralysis of the shoulder girdle muscles leads to subluxation of the shoulder joint with further decrease in stability (Hartwig et al., 2012). Inability to stabilise the scapula is accompanied by upper-limb pain and pathology. Patients who present with shoulder and upper-limb symptoms demonstrate poor dynamic scapula control (Brukner et al., 2012). Shumway-Cook and Woollacot (2012) maintain that instability at one joint requires provision of stability at the adjoining segments.

2.4.3 Shoulder pain post-stroke

Pain is a complication that affects the upper limb frequently with regard to independent ADL, function and/or HRQoL. Pain further could decrease the patient's functional abilities and motivation to train during therapy sessions; therefore, during physiotherapy the prevention of shoulder pain should be incorporate (Brewer et al., 2012; Price, 2003). Pain can occur as early as two weeks post-stroke (Khatri & Kalra, 2012). Pain is more complex than simply being a sensory experience resulting from the interaction of physical, emotional, cognitive, behavioural and contextual factors (Huguet et al., 2010; Gilmore et al., 2004; Price, 2003). Shoulder pain negatively affects functionality and HRQoL specifically related to transfers, balance, ADL and hand function. Pain should not be ignored, especially during treatment by therapists (Lang et al., 2012; Huguet et al., 2010; Dromerick et al., 2008). Patients presenting with pain at discharge, or after two months post-stroke are more likely to present with continuous pain. The exact cause of hemiplegic shoulder pain remains unclear, but could be ascribed to a combination of factors such as abnormal muscle tone,

subluxation and a decreased ROM, or capsular tightness (Lang et al., 2012; Huguet et al., 2010).

Abnormal tone (both hypertonicity and hypotonicity) has been suggested as a contributing factor in hemiplegic shoulder pain. Increased muscle tone may cause pain by producing sustained traction on periosteal muscle attachments and could interfere with the normal scapula–humeral rhythm, increasing the risk of contractures. Consequently, there is a vicious cycle of reduced movement and increased restriction, with disuse atrophy and osteoporosis occurring as late events (Sackley et al., 2008). Flexor tone predominates in the hemiplegic upper extremity and results in scapular retraction and depression as well as internal rotation and adduction of the shoulder. A shortened agonist in the synergy pattern becomes stronger and the constant tension of the agonist can become painful. Stretching of these tightened spastic muscles causes more pain. Shortened muscles inhibit movement, reduce range of motion, and prevent other movements especially at the shoulder where external rotation of the humerus is necessary for arm abduction greater than 90 degrees (Sackley et al., 2008). Due to abnormal muscle tone or structural changes there may be a decrease in range of motion (specifically, external rotation), it is often difficult to distinguish whether pain is arising from capsulitis or spasticity, or from a combination of both. Spasticity may be painful, interfere with functional recovery in the upper limb and influence treatment. Soft-tissue injuries may result from uncontrolled range of motion exercises, poor positioning of the hemiplegic patient, or improper transfer techniques. Patients with poor cognition, neglect, and other sensory deficits tend to be predisposed to traumatic injuries to the affected extremity (Adey-Wakeling et al., 2013; Huang et al., 2010; Sackley et al., 2008; Paci et al., 2007; Snels et al., 2000).

Post-stroke, subluxation of the Gleno-humeral joint is caused by hypotonicity in the upper limb. This results in the upper limb hanging constantly, stretching and straining the joint capsule, and causing damage to the muscles and ligaments as well as causing impaired blood circulation (Gilmore et al., 2004). To prevent shoulder subluxation the upper limb must be supported optimally in the initial hypotonic stage (Gilmore et al., 2004; Price, 2003). In hypo- and hypertonic stages, changes may

occur in the alignment of the shoulder complex. In addition, weakness in the muscles may result in failure to rotate the scapulae and humerus during movement which, in turn, causes impingement. During passive elevation of the upper limb the risk of rotator-cuff damage may be increased. Traction damage to various nerves surrounding the shoulder girdle may also be caused due to the weight of the unsupported upper limb (Gilmore et al., 2004; Price, 2003). Strengthening the rotator cuff in the presence of instability therefore is thought to be critical because it stabilises the humeral head within the glenoid fossa (Merrill et al., 2009).

Hemiplegic shoulder pain also may be related to rotator-cuff tears, brachial plexus injuries, shoulder–hand syndrome and/or other pre-existing pathological conditions (Dromerick et al., 2008; Gilmore et al., 2004; Price, 2003). However, a study by Heitzner and Teasall (1998) “found no significant difference in the frequency of rotator cuff tears in the affected and unaffected shoulders of patients with hemiplegia.” Furthermore, these researchers found a correlation with shoulder pain only before stroke, and not post-stroke (Heitzner & Teasall, 1998).

Post-stroke brachial plexus injuries could occur due to hypotonicity in the upper limb. During neck stretches (up and away) from the injured shoulder, damage to the upper nerves of the brachial plexus tends to occur in a combination with a distraction on the upper limb (Atzmon & Ring, 2008; Gilmore et al., 2004). Forced upper-limb movements above the head are more likely to injure the lower nerves. After stroke this type of nerve injury may be caused by stretching or traction during transfers, ADL or handling of the patient. Due to the severity and location of a brachial plexus injury the signs and symptoms may vary greatly (Swanik et al., 2010; Atzmon & Ring, 2008; Gilmore et al., 2004; Price, 2003).

Signs and symptoms of a painful shoulder (shoulder-hand syndrome) normally develop between one and six months post-stroke with pain and loss of ROM in the shoulder (Dromerick et al., 2008; Gilmore et al., 2004). Later, pain may extend to the distal part of the extremity. Characteristics of shoulder–hand syndrome include deep, burning pain, changes in skin colour and temperature, limitation of movement and oedema of the arm and/or hand (Dromerick et al., 2008; Gilmore et al., 2004). The

incidence of shoulder-hand syndrome is approximately 13–27% in stroke patients and the syndrome affects the general functionality of the patient such as bed mobility, ADL and transfers (Gilmore et al., 2004). This syndrome develops in three phases, namely acute (phase I), dystrophic (phase II) and atrophic (phase III) phases and may be caused by biomechanical changes of the hemiplegic shoulder (Dromerick et al., 2008; Gilmore et al., 2004). Partial subluxation of the gleno-humeral head is caused by instability and the paresis of the shoulder girdle muscles. Chronic pain may develop due to repetitive micro-traumas of the shoulder joint leading to the development of an abnormal, regional sensory-sympathetic reflex arch (Dromerick et al., 2008; Gilmore et al., 2004).

Other pre-existing pathological conditions also might cause pain post-stroke (Gilmore et al., 2004). Normal aging may also lead to decreased ROM due to postural or biomechanical changes. Before stroke, these symptoms may be asymptomatic, but after stroke they may lead to shoulder pain (Gilmore et al., 2004).

2.4.4 Other impairments and activity limitations post-stroke

Upper-limb function includes reaching for and grasping of objects and is required in many ADLs. Post-stroke the upper limb impairments which influence reaching and grasping include limited muscle activation and reduced muscle weakness, abnormal movement synergies between the shoulder and elbow muscles that lead to a decrease in ROM, decreased coordination between the upper-limb joints, decreased fluency of movement, and incoordination between the reaching and grasping movements (Lang et al., 2012; Smith, 2012).

Specific impairments that affect grasping include increased tone in finger flexors, impaired voluntary activation of both the extensors and flexors of the fingers, and an inability to activate muscle groups independently, resulting in abnormal movement patterns and reduced active ROM (Lang et al., 2012; Smith, 2012). Stroke patients thus struggle with selective movement of the upper limb due to damage to the corticospinal system (Lang et al., 2012). The absence of selective movement may lead to associated reactions and further impairment of upper-limb movement as a

result of abnormal synergies of movement (Lang et al., 2012). Selective movement is required because the shoulder has to stabilise proximally for optimal distal hand function (Lang et al., 2012; Davies, 2000).

The difficulty with and/or loss of motor function in the affected upper limb may be complicated further by limited ROM of the shoulder, loss of sensory function and increased muscle tone (Takeuchi & Izumi, 2013; Brewer et al., 2012; Thielman & Bonsall, 2012). Sensory impairments post-stroke are associated with stroke severity and are believed to affect participation during rehabilitation (Brewer et al., 2012). Clinically, the presence of severe unilateral neglect also may influence patients' ability to interact with therapists and with their surroundings. Stroke patients with unilateral neglect may ignore objects on the one side and attend to only one side of their bodies (Takeuchi & Izumi, 2013). The differences between the upper and lower limb, with regard to specificity, the extent of cortical representation and the recognition of spasticity (which occur more commonly in the upper limb), influence the rehabilitation process and outcome (Pattern et al., 2006). The lack of spontaneous stimulation of the affected limb during functional activities may also affect the recovery process. In such a case a patient may choose to make only use of the unaffected limb during ADL (Brewer et al., 2012).

Abnormal muscle tone post-stroke has a negative effect on upper-limb function as it influences the initiation of movement (Lang et al., 2012; Davies, 2000). Sensory impairments such as decreased or abnormal sensation or proprioception may also contribute to hampered upper-limb function seeing that the nervous system has difficulty controlling, monitoring and correcting movements (Lang et al., 2012; Davies, 2000).

Each of the impairments outlined above may occur in isolation, but more often they occur in combination (Lang et al., 2012; Davies, 2000). The possibility of a correlation between these impairments, the severity of the paresis, hypertonicity and the selective movement also exists (Lang et al., 2012; Davies, 2000). For optimal distal hand function to occur selective movement is required and the shoulder has to stabilise proximally (Davies, 2000). Only 30–66% of patients affected by stroke

recover the use of their affected upper limb in functional activities (Krug & McCormack, 2009).

2.5 Impact of upper limb involvement on function and HRQoL post-stroke

Stroke-related disability may greatly impact patients' HRQoL and their ability to live independently because it limits participation in social and occupational roles as well as leisure activities (Morris et al., 2013; De Weerd et al., 2012) the greater the disability (physical and cognitive impairments), the lower the experience of HRQoL (De Weerd et al., 2012; Haley et al., 2011).

Post-stroke 85% of patients present with initial motor and/or sensory deficits of the upper limb (Harris et al., 2010). The improvement of upper-limb function is poor, and in 55–75% of cases the patient still presents with poor upper-limb functionality three to six months after the initial incident, depending on initial severity (Morris et al., 2013; Lang et al., 2012). Harris et al. (2010) state that upper limb function is vital for the completion of many ADLs, as well as for socialisation and for HRQoL (Harris et al., 2010). Research has shown that even patients who fully recover post-stroke do not integrate the affected upper limb into ADL – this reduces their independence and consequently, their community participation (Lang et al., 2012).

2.5.1 Factors affecting function and HRQoL after stroke

Key factors associated with HRQoL may be stroke specific, including communication, cognition and physical factors such as independence in daily life, motor impairments and fatigue (Morris et al., 2013; De Weerd et al., 2012; Kissela, 2006). Other factors such as depression, inadequate social support, negative demographics and dependency in ADL also impact HRQoL (Morris et al., 2013; Rangell et al., 2013; De Weerd et al., 2012; Kissela, 2006).

Research has identified physical disability, which includes poor or no upper-limb function as a determinant of HRQoL among stroke survivors (Lang et al., 2012).

Females appear to have poorer perceived physical ability, which could lead to increased dependence on family or caregivers for assistance with ADL (De Weerd et al., 2012; Haley et al., 2011). A part of improved HRQoL and participation is to provide for family, and one of the primary life roles of females is to take care and provide for their family. Post-stroke it may take longer to execute basic ADL and/or functional activities, which could affect the quality and/or quantity of activities an individual is able to perform daily.

The absence of an appropriate caregiver to assist with care also could result in a decrease in HRQoL (Haley et al., 2011). Dominant-sided hemiplegia reduces independence with regard to ADL more significantly (Rangell et al., 2013; De Weerd et al., 2012) which, in turn, may increase challenges with regard to general mobility and driving a motor vehicle (Brewer et al., 2012). Decreases in function lead to an increase in dependence, causing emotional reactions and social isolation which, ultimately, debilitate HRQoL (Brewer et al., 2012).

Stroke is ranked second in causes of cognitive impairment (Mellon et al., 2015), and may lead to a decrease in functional capacity; therefore, it affects rehabilitation outcomes and the rehabilitation process (Brewer et al., 2012; Barreca et al., 2003). Cognitive impairment has been associated independently with reduced HRQoL in stroke survivors over time (Jeong et al., 2012). Cognitive impairments include memory loss, impaired executive functioning, inattention, altered concentration, decreased alertness and visuospatial impairment, and could lead to decreased transfer of learning which might interfere with the execution of tasks during therapy sessions. The ability to make decisions, plan, use judgement, and being able to self-correct are all essential for carrying out complex ADL. Cognitive dysfunction results in impaired overall function and distress in patients and carers and has been associated with increased mortality (Mellon et al., 2015; Rangell et al., 2013).

A number of conditions associated with communication are found in patients post-stroke, including dysarthria, apraxia and aphasia. Patients who experience such speech difficulties are more prone to depression, poorer rehabilitation outcomes and higher mortality (Poslawsky et al., 2010). Aphasia presents in 20–40% of stroke

survivors and refers to a condition where language reception, expression or both are affected to varying degrees due to neurological damage (Brewer et al., 2012; Poslawsky et al., 2010). Communication disorders may have a negative impact on patients' HRQoL and their rehabilitation and recovery. This is largely because of patients becoming frustrated with their inability to communicate properly to indicate basic needs, to express themselves during treatment sessions or to socialise (Poslawsky et al., 2010).

Post-stroke mood disorders such as anxiety and depression, also are frequently present and strong evidence ensuring from many studies indicates that these mood disorders influence the HRQoL (Morris et al., 2013; Takeuchi & Izumi, 2013). These emotional factors may lead to reduced motivation and the ability to continue with rehabilitation activities (Brewer et al., 2012).

Morris et al. (2013) states that energy levels may be predicted by anxiety, with patients who are more anxious being more fatigued. Post-stroke fatigue affects between 40% and 70% of patients and is not necessarily related to activity level or quality of sleep. The presence of fatigue post-stroke is linked to depression in some patients. Fatigue has many possible causes and has a negative impact on rehabilitation potential (Morris et al., 2013; Takeuchi & Izumi, 2013). Fatigue does not always improve with rest and may make patients feel that they are not in control of their recovery. Post-stroke participation in ADLs and rehabilitation are negatively impacted by the lack of energy the patients experience and the need for regular rest (Brewer et al., 2012; Barreca et al., 2003). Other factors that may influence the level of fatigue are irregular sleep cycles, some medications, and physical post-stroke symptoms such as upper-limb weakness, pain and paralysis which require more energy to perform movement and ADLs (Brewer et al., 2012; Barreca et al., 2003).

Social factors such as support from friends and family, as well as interaction with rehabilitation staff, play an integral role during the rehabilitation process. The more positive support a patient experiences during the rehabilitation, the more cooperative the patient usually is during therapy sessions. It is important that patients be well informed of the expectations during these sessions (Brewer et al., 2012; Barreca et

al., 2003). The burden of stroke lies in its high morbidity, which leaves up to 50% of survivors chronically disabled, and its impact on the family and on their socio-economic status (Takeuchi & Izumi, 2013). Successful rehabilitation following stroke plays a key role in reducing long-term complications, restoring maximal function and improving HRQoL (Brewer et al., 2012; De Weerd et al., 2012).

2.6 Rehabilitation post-stroke

Neurological recovery is often the result of brain recovery/reorganization and can be influenced by rehabilitation. Post-stroke neurological recovery happens mostly within the first three months, where after it may be slower for up to one year. Improvement in function may occur during the period six months to three years post-stroke. Rehabilitation is a central part of reducing long-term disability post-stroke. With rehabilitation, optimal functional recovery to the point of community reintegration may be achieved by improving impaired movement and function, reducing the disability and encouraging patients to partake in ADL (Brewer et al., 2012). The skill of the rehabilitation team and timing of rehabilitation also are considered as playing a key role during the recovery of the patient (Brewer et al., 2012).

Several factors may influence the recovery process of the upper limb post-stroke and these vary from person to person. Most of these factors also affect the HRQoL of the patients as discussed earlier. These factors may be divided into patient and environmental factors. Stroke rehabilitation is influenced by physical, emotional, social and therapeutic factors (Rangell et al., 2013; Brewer et al., 2012; Barreca et al., 2003). Patient factors include the extent of brain damage, the development of complications, previous functionality and co-morbidities, as well as the patient's response to motor learning and motor recovery in the upper limb which may shift the rehabilitation focus to other areas (Barreca et al., 2003). Environmental factors include the availability of rehabilitation resources, time constraints regarding therapy and the availability and quality of support from family and friends (Brewer et al., 2012).

Treatment aims during the acute and sub-acute phase of stroke mainly include the learning and relearning of movements necessary to perform ADLs (Brewer et al., 2012; Barreca et al., 2003). Reintegration of the affected upper limb into ADLs is important, depending on the type of functional gains (Brewer et al., 2012; Barreca et al., 2003). Regular practice of the skills or ADLs is necessary for the promotion of motor learning and skills training because motor recovery post-stroke is directly related to neural plasticity.

Neural plasticity involves developing new neuronal pathways, acquiring new functions, and compensating for impairment (Takeuchi & Izumi, 2013; Brewer et al., 2012). Neural plasticity is the ability to form memories, adapt and learn during experience and involves the changing of the structure, function and organization of neurons or nerve cells (in the remaining cortical tissue) and the formation of new pathways in response to these experiences (Warraich & Kleim, 2010). The adult brain can create new neurons based on outside stimuli, which contributes to recovery of function post-stroke. Reorganization of the brain post- stroke is dependent not only on the lesion site, but also on the surrounding brain tissue and on remote locations that have structural connections with the injured area. These new neurons require support from neighbouring cells, blood supply, and connection with other neurons to survive (Warraich & Kleim, 2010; Wieloch & Nikolich, 2006; Gu, 2002). Rehabilitation involving neuroplasticity principles requires repetition of task and task-specific practice leading to change in the primary motor cortex. Motor areas that were not involved primarily during the specific function are recruited to assist with the movement; the unaffected hemisphere has the capacity to contribute to movement on the affected side. During the early stages post-stroke there is increased motor cortex activation of both hemispheres but more on the unaffected hemisphere. Thus, post-stroke motor activity in the affected upper limb results in recruitment of cortical areas along the infarct rim, secondary motor areas in the contralateral (unaffected) hemisphere and ipsilateral (affected) hemisphere motor areas (Enzinger et al., 2008; Jankowska & Edgley, 2006).

Post-stroke patients may make use of compensatory movements of the unaffected side or trunk for functionality and in the process inhibit normal movement patterns of

the affected side (Takeuchi & Izumi, 2013; Brewer et al., 2012; Barreca et al., 2003). The correct and appropriate goals and exercises for each patient should be identified to prevent this during rehabilitation (Takeuchi & Izumi, 2013).

Evidence presented by Brewer et al. (2012) and De Weerd et al. (2012) indicate that increased time spent on exercise during the first six months post-stroke results in significant improvements in walking ability and speed as well as extended ADLs. The skill of the rehabilitation team post-stroke and other therapeutic factors, including an early start with rehabilitation may also influence the rehabilitation process (Brewer et al., 2012). The earlier the rehabilitation process is commenced the better the stimulation and the sooner neural plasticity will start resulting in better rehabilitation outcomes. A skilled therapist may have a better understanding of the condition and make use of a combination of treatment modalities best suited to the patient (Brewer et al., 2012; Barreca et al., 2003) which will optimise functional outcomes.

The aim of stroke rehabilitation is to reduce stroke-related disability and this is a dynamic process. It is recommended that stroke rehabilitation be employed by multidisciplinary teams that can support active patient participation (Brewer et al., 2012). Motor learning is important and the rehabilitation should focus on meaningful tasks, repetition and intensive programmes (Takeuchi & Izumi, 2013; Brewer et al., 2012). However, there are varying degrees of recovery post-stroke due to different mechanisms underlying motor recovery (Takeuchi & Izumi, 2013).

2.6.1 Upper-limb rehabilitation post-stroke

The rehabilitation of the hemiplegic upper limb remains a challenge, in spite of the many therapeutic modalities and approaches that are available (Brewer et al., 2012). The lack of positive findings regarding outcomes of stroke rehabilitation in the literature could be ascribed to numerous reasons, such as the low statistical power of studies, the heterogeneity of study populations and the limited response of outcomes measures (Van der Lee et al., 2001).

Stroke rehabilitation of the upper limb within the first three months after the incident mainly consists of passive (non-specific) movement approaches or compensatory training of the affected upper limb (Brewer et al., 2012). In order to reduce spasticity, which is prevalent post-stroke (affecting between 20% and 40% of patients) (Sommerfeld & Welmer, 2012; Urban et al., 2010; Watkins et al., 2002), and to maintain ROM, passive movements and stretching may be applied by the caregiver or therapist (Takeuchi & Izumi, 2013; Brewer et al., 2012). Slow controlled passive movements may also assist in creating awareness and increasing muscle control (Takeuchi & Izumi, 2013; Brewer et al., 2012; Van der Lee et al., 2001). Various techniques may be used to optimise joint position and to maintain or regain soft tissue length. Stretching may help to prevent contracture formation and, although well-accepted as a treatment strategy, there are contradictory findings with regard to the effects and the outcome of this treatment (Winter et al., 2011; Katalinic et al., 2010).

Well-timed activation of co-contraction of the agonist and the antagonist muscles plays a vital role in the rehabilitation of hemiplegic patients (Malcolm et al., 2009; Luft et al., 2004). For the upper extremity, reaching is commonly affected (Malcolm et al., 2009; Luft et al., 2004). This is largely due to impaired timing (delay in initiation of movement) of the agonist and antagonist muscles which can result in co-contraction as a result of the overlapping of the opposing muscle activation (Malcolm et al., 2009; Luft et al., 2004). Rhythmic reaching and retrieving actions may be retrained by making use of a metronome to cue the patients (Malcolm et al., 2009; Luft et al., 2004). During the re-education of gait post-stroke auditory cueing has been successfully used, and is more commonly used during gait (lower-limb) than upper limb training. Simultaneous and alternating bilateral upper-limb movements could produce a facilitatory effect from the unaffected to the affected upper limb, due to the coordinated function which occurs in the brain (Malcolm et al., 2009; Luft et al., 2004).

In a study by Pattern et al. (2006) a hybrid upper-extremity rehabilitation intervention consisting of combined power and functional task-specific training resulted in increased strength. A positive effect was identified on the functional, psychological

and clinical outcomes of the upper limb (Pattern et al., 2006). Dynamic, high-intensity resistance training of the upper limb also resulted in marked improvements (Pattern et al., 2006). This intervention was also found to influence the impairments, activities and the participation of patients with stroke positively and resulted in decreased joint pain and spasticity (Pattern et al., 2006).

Forced use of the upper limb during intensive training techniques has the potential to significantly improve upper limb function with regard to ADLs (Brewer et al., 2012). Auditory cueing also may be used for the improvement of the movements when combined with, for example, constraint-induced therapy and bilateral rhythmical training (Malcolm et al., 2009; Luft et al., 2004).

Another common goal of therapy is weight-bearing or close-chain exercises for the affected limb in order to try to facilitate normal movement patterns through correct biomechanical alignment and muscle activation (Bakhtiary & Fatemi, 2008). Weight bearing over the hemiplegic side can be used to activate muscle activity, increase stability, normalise tone, maintain muscle length and provide sensory input to the involved side through proprioceptive stimulation (Lang et al., 2012; Davies, 2000). Weight-bearing exercises may be used to reduce the risk of injury as joint compression and approximation act to enhance muscular co-contraction about the joint-producing dynamic stability (Bakhtiary & Fatemi, 2008). The objective is to facilitate normal movement patterns by applying approximation through the weight-bearing limb. Postural and trunk control may be activated by means of facilitation and the re-education of weight-bearing and non-weight bearing movements of the upper limb. These techniques may help decrease the learning of abnormal movements by allowing the patient to practise normal patterns of movement (Lang et al., 2012; Davies, 2000).

Weight bearing has various positive effects in all the stages of recovery and should be started with as early as possible (Lang et al., 2012). Fear and neglect will decrease as the patient becomes more aware of the affected side. Positioning in side-lying (weight bearing) on the affected side in bed can be used in combination with inhibitory treatment techniques. Weight bearing is beneficial even in patients

who already have been post-stroke for a long period and should be incorporated in ADL (Lang et al., 2012). Weight bearing is a dynamic process during which the patient is taught to activate muscles in the trunk by moving body weight over from the stable upper limb (Lang et al., 2012; Davies, 2000). Muscles in the upper limb and hand lengthen and shorten to maintain the upper limb on the support surface during trunk movements in a weight bearing position. Since the use of the arm for weight support does not require fine motor control, even patients with severe weakness and loss of motor control can learn to use their hemiplegic arms to support body weight (Lang et al., 2012; Davies, 2000). This can be done by placing the hemiplegic arm with forearm on a table, for example, during ADLs commonly performed at a table, such as eating, reading and writing. Weight bearing on an extended arm is more difficult and requires control of the elbow and wrist joints as well as control of the trunk and shoulder girdle (Lang et al., 2012; Davies, 2000). It is used with patients who have more selective control and is often applied while the patient is sitting with the affected arm is bearing weight with elbow extension at the side of the body (Lang et al., 2012; Davies, 2000). Controversy exists as most therapy programmes for the shoulder joint involve open-chain exercises, as the upper limb function involves open kinetic chain activities. Treatment of the shoulder joint should be functional and should allow for free active movements (Lang et al., 2012; Bakhtiary & Fatemi, 2008). Van Vliet and Wulf's (2006) findings indicate that visual and auditory feedback can be used to provide information during the rehabilitation of weight distribution for balance retraining as well as re-education of the sit-to-stand movement. Subramanian et al. (2010) report that external feedback may be given in the following ways: verbally, making use of virtual environments, videotaping, robotics or using auditory input, and may lead to improved motor learning of the affected limb.

Lastly, therapy focuses mainly on motor retraining post-stroke (Hunter & Chrome, 2002). However, there is an accompanying sensory impairment that has an adverse effect on the functional outcome of the patient (Hunter & Chrome, 2002). Brewer et al. (2012) report that sensorimotor stimulation during the motor and functional recovery of the hemiplegic upper limb may increase upper-limb function in the acute phase but no changes have been seen in superficial or deep sensation.

Upper-limb rehabilitation techniques include the following: functional and task specific therapies, non-invasive brain stimulation (NIBS), action observation, virtual reality (VR) training, brain-computer interface (BCI), splinting, and botulinum toxin (Takeuchi & Izumi, 2013; Brewer et al., 2012). During rehabilitation emphasis should be placed on functional and task-specific therapies that focus on the specific functional needs of the patient with the aim of improving independence (Brewer et al., 2012; Pattern et al., 2006).

2.6.2.1 Upper-limb functional and task-specific therapies

Upper-limb functional and task specific therapies improve motor learning and promote neural plasticity which, in turn, promotes the recovery to functioning at behavioural level (Brewer et al., 2012; Pattern et al., 2006). Task-specific training may be used effectively to recover motor behaviours of the upper limbs and lower limbs after stroke (Brewer et al., 2012). Treatment principles should be directed at preventing biomechanical changes, decreasing stiffness, reducing spasticity and retraining and facilitating function (Hunter & Chrome, 2002). Many therapeutic interventions exists- all proven to be valuable, but it is also indicated that these interventions should not be used in isolation and render better results when combined with other modalities (Takeuchi & Izumi, 2013; Brewer et al., 2012). Only a few of these interventions will be discussed, as the researcher focussed on those that are more commonly used.

Upper-limb functional and task-specific therapies include the following: constraint-induced movement therapy (CIMT), mirror therapy, robotic training, transcutaneous neuromuscular electrical stimulation, biofeedback and bilateral arm training (Takeuchi & Izumi, 2013; Brewer et al., 2012). These will be described briefly in the next section.

a) Constraint-induced movement therapy (CIMT)

CIMT forces patients to use the paretic upper limb instead of the non-paretic upper limb to execute ADLs while the non-paretic limb is immobilised or restrained with a

sling or glove (Takeuchi & Izumi, 2013). This principle is used to overcome the "learned non-use" of the hemiplegic affected limb. The repetitive training of the paretic limb and constraint of the non-paretic upper limb are important for promoting neural plasticity, improvement in upper-limb motor function, dexterity and the patient's self-reported arm-hand use (Takeuchi & Izumi, 2013). However, during restraining of the unaffected upper limb the patient will be less functional and this therapy requires much effort. CIMT has been used successfully in the rehabilitation of movement of the affected upper limb post-stroke (Takeuchi & Izumi, 2013; Kwakkel et al., 2008).

Limiting factors during CIMT may be the required practice intensity and duration of restraint, but these may be overcome by structured functional practice sessions and other therapies. The patients also need some selective hand movement (slight wrist and finger extension), good balance, and good cognitive and communication skills (Wolf et al., 2010; Dromerick et al., 2009). For patients with the lowest motor functioning, CIMT does not improve movement at the shoulder and elbows as they have little or no ability to move the fingers and there is no adequate motor basis for carrying out training of hand function (Wolf et al., 2010; Dromerick et al., 2009). Variable outcomes were also noted depending on the severity of initial impairment and the phase of the rehabilitation. CIMT is a beneficial treatment approach for those stroke patients with some active wrist and hand movement. Thus CIMT is not a complete answer to motor recovery post-stroke (Wolf et al., 2010; Dromerick et al., 2009; Wolf et al., 2006; Barreca et al. 2003).

b) Mirror therapy

Mirror therapy makes use of visual stimulation; the illusion of movement in the affected limb is created by the reflection of the moving unaffected limb while the affected arm is hidden behind the mirror (Thieme et al., 2012; Rothgangel et al., 2011). Movements of the non-affected limb give the illusion that the affected limb is moving and may compensate for a reduced or absent proprioceptive input through sensory feedback and motor intention. Mirror therapy may improve ADLs, reduce

pain and improve visual spatial neglect (Thieme et al., 2012; Rothgangel et al., 2011; Moseley, 2006).

However, little is known about the kind of stroke patients who are likely to benefit from mirror therapy and how such a therapy preferably should be applied (Rothgangel et., 2011). Mirror therapy previously was used for the treatment of phantom limb pain as a method to “re-train the brain” as a means of enhancing upper-limb function following stroke and to reduce pain (Moseley, 2006). Evidence about mirror therapy improving motor function post-stroke is conflicting, as is evidence that it does not reduce spasticity. Positive results were found in cases where mirror therapy was combined with other interventions post-stroke (Rothgangel et al., 2011; Cacchio et al., 2009a; Cacchio et al., 2009b).

c) Robotic training

Robotic training devices move limbs passively, while providing assistance or resistance to movement of a single joint or controling of intersegmental co-ordination. Robotic training enhances repetitive task-specific training and can increase motor learning, motor control and strength (Kwakkel et al., 2008). Robotic training has several advantages during rehabilitation, for example, repeatability, controllable assistance or resistance during movements, and objective and quantifiable measures of performance. It provides intensive sensorimotor treatment and task-oriented training (Lo et al., 2010; Kwakkel et al., 2008). Furthermore, robotic training permits passive or active-assisted movements and counter-resistance, which assist the patient in some movement tasks by means of bio-feedback and measuring changes in movement kinematics and forces (Lo et al., 2010; Kwakkel et al., 2008). Robotic training also can assist with passive range of motion to temporarily reduce hypertonia or resistance to passive movement (Lo et al., 2010; Kwakkel et al., 2008).

Neurological rehabilitation may be provided by means of robotic training devices without increasing the burden on therapists or increasing healthcare costs. A systematic review by Prange et al. (2006) on recovery of the hemi-paretic arm indicated improved short- and long-term motor function of the paretic shoulder. In

contrast, limited effects of robotic therapy on the upper limb of individuals post-stroke have been demonstrated by research. Despite the potential benefits, research has indicated that, even with robotic training, compensatory movement strategies still are observed and need to be controlled. In addition, there is a lack of patient engagement during the use of robotic training (Lo et al. 2010; Kwakkel et al., 2008; Lum et al., 2002). The robot can also assist when the patient has active movements, but cannot complete a movement independently. Lo et al. (2010) report that the robot-assisted arm training improved generic ADL, but did not improve the muscle strength of the partially paralysed (paretic) upper limb. Robotics may be appropriate for patients with dense hemiplegia, as well as patients with impaired motor function by providing resistance during the movement. Sensorimotor training during robotic training may improve upper-limb function and motor outcomes of the shoulder and elbow, but does not improve motor outcomes of the wrist and hand (Lo et al., 2010; Kwakkel et al., 2008).

d) Electrical stimulation

Electrical stimulation is typically administered by means of two methods, functional electrical stimulation (FES) and transcutaneous electrical nerve stimulation (TENS) (Takeuchi & Izumi, 2013). The distinction that usually is made between these two forms of treatment is that lower intensity, higher frequency stimulation is associated with TENS and is more commonly used to treat pain (Church et al., 2006). FES has been described as electrical stimulation applied to the nerves or muscles affected post-stroke, with the goal of strengthening muscle contraction and improving motor control during a functional task (Roy et al., 2011). Electrical stimulation can be applied to improve neuromuscular function of the upper limb and hand by strengthening the muscles, the increase of motor control, reduction of spasticity, decreasing and limiting of pain and increasing and maintaining optimal range of motion (Takeuchi & Izumi, 2013). Feedback (cutaneous, muscle and joint proprioceptive) obtained during motor activation by means of electrical stimulation helps with recruiting and activating new pathways to compensate for the impaired pathways, which in turn may help with motor recovery (Roy et al., 2011; Hardy et al., 2010).

Various studies have determined a positive effect of electrical stimulation in the restoration of motor function and reduction of pain post-stroke (Christensen & Grey, 2013; Hara et al., 2013; Takeuchi & Izumi, 2013). Most of the studies reported a benefit associated with electrical stimulation, although there was variability in the outcomes assessed: range of motion, muscle tone, EMG activity, shoulder subluxation, shoulder pain and muscle function. However, in a study by Church et al. (2006) no positive effect was found on the use of FES. These authors suggest that the therapy may be associated with harm and may worsen arm function, especially among those with severe paresis. Possible reasons included abnormal afferent stimulation and the inhibition of plasticity; movement resulting in early over-use of the affected upper limb; less awareness with increased severity of stroke and unawareness of adverse effects; overstimulation producing tiredness; and possible less use of the upper limb as the FES produced movement (Church et al., 2006).
Conflicting evidence thus exist that treatment with electrical stimulation in the upper limb might improve motor recovery and performance of ADLs (Pollock et al., 2014, Roy et al., 2011). Various stimulation protocols may be used and when combined with rehabilitation therapies may help to improve motor recovery (Takeuchi & Izumi, 2013).

e) Biofeedback

Biofeedback has been used in rehabilitation aimed at the recovery of motor function post-stroke (Takeuchi & Izumi, 2013; Brewer et al., 2012). Biofeedback provides enhanced awareness of movement or function, with the goal of improving voluntary control of that movement or function (Molier et al., 2011). Feedback consists of intrinsic (person's own sensory-perceptual information) and extrinsic feedback (feedback provided from the environment, verbal and non-verbal) (Takeuchi & Izumi, 2013; Brewer et al., 2012). Biofeedback provides auditory and/or visual stimulus to the patient (generated from muscle activation) via electrodes placed on the skin, which can influence the patient's use of their affected limb positively (Brewer et al., 2012; Van Vliet & Wulf, 2006). EMG biofeedback has shown mixed results, and its cost-effectiveness is uncertain (Molier et al., 2011).

f) Bilateral arm training

Bilateral arm training is a technique whereby patients practise the same activities with both upper limbs simultaneously. Theoretically, the use of the intact limb helps to promote functional recovery of the impaired limb through facilitative coupling effects between the upper limbs. Practising bilateral movements may allow the activation of the intact hemisphere to facilitate the activation of the damaged hemisphere through neural networks linked via the corpus callosum (Stoykov et al., 2009; Kwakkel et al., 2008; Summers et al., 2007). Different forms of simultaneous bilateral arm training are available. Some use 'free' arm movements, and others use mechanical or robotic devices to drive active or passive movement of the affected limb through identical movement of the less-affected upper limb (van Delden et al., 2009). Bilateral exercises may facilitate the inhibition of asymmetry of the post-stroke hemispheric cortex and increase the excitability that promotes the improvement in motor control of the affected upper limb (Stoykov et al., 2009).

Bilateral arm training with auditory cueing (BACTRAC) has shown good results in motor learning that promotes functional gains in the hemiplegic upper limb (Stoykov et al., 2009). In patients with chronic upper limb hemiplegia improvement has been noted on several key measures of sensorimotor impairment, functional ability (performance time), and functional use of the affected upper limb. The results were maintained for two months after the training. Bilateral upper limb training protocols described in the literature are diverse. Aspects included in some protocols were: repetitive reaching with the hand fixed, repetitive training of isolated muscles and functional exercises that included the whole upper limb (Lodha et al., 2012; Stoykov et al., 2009). In a few of the studies rhythmical auditory cueing was combined with repetitive reaching with the upper limb fixed (Stoykov et al., 2009). Bilateral upper limb training may improve the activation of the unaffected hemisphere to facilitate the activation of the affected hemisphere to promote neural plasticity for the motor control of the affected limb (Summers et al., 2007).

Stoykov et al. (2009) found different benefits for bilateral and unilateral groups. Positive mechanisms that possibly accompany bilateral training involve the improvement of proximal stability and postural stability which could lead to the improvement of upper-limb control (Stoykov et al., 2009). A meta-analysis on upper limb robotics suggests that distally oriented repetitive bilateral arm training is more effective than a more proximally oriented approach (Kwakkel et al., 2008). However, although there is evidence that BATRAC is an effective way to improve upper limb function in chronic stroke patients contradictory studies also were found (Van Delden 2009; Richards et al., 2008).

g) Mental practice and virtual reality training

Mental practice is based on conscious activation of brain regions and networks involved in movement preparation and execution (Page et al., 2007). Therapist-guided mental practice indicated increased dexterity and changes in patterns of cortical activation in chronic stroke patients (Page et al., 2007). Mental practice can be used early in the rehabilitation process and even in severely paretic patients, although it may be difficult in patients with left parietal or left lateral prefrontal lesions. Mental practice may result in improved motor and ADL functioning post-stroke therapy and may be used at any stage of recovery. However, during mental practice training, mental rehearsal often is combined with physical practice when possible. Mental practice indicated improvement in motor function in the affected upper limb of chronic stroke patients and also appeared to provide benefit when combined with the co-intervention of modified constraint-induced therapy (Page et al., 2008).

Virtual reality training provides multimodal, interactive, and realistic 3-dimensional environments. The evidence of the effectiveness of virtual reality training in stroke rehabilitation thus far is limited (Da Silva et al., 2011; Saposnik et al., 2010). Virtual reality enables people to engage in activities within an environment which appears and feels similar to real-world objects and events, using devices such as a keyboard and a mouse, or through multi-modal devices such as a wired glove. Virtual reality may also be used with robotic devices that assist or resist movement. Nintendo Wii gaming technology represents a potentially effective alternative to promote motor

recovery and a rehabilitation gaming system that facilitates the functional recovery of the upper extremities (Da Silva et al., 2011). But still, there is conflicting evidence about whether only mental practice and virtual reality training may improve upper-extremity motor and ADL performance following stroke (Pollock et al., 2014).

2.7 Outcomes measures

Post-stroke assessment of patient function, independence and HRQoL is of great importance (Brewer et al., 2012). Outcomes measures are also valuable in monitoring progress and can be used as motivation for therapy and/or rehabilitation (Brewer et al., 2012). No single scale assesses all aspects of stroke disability or predicts recovery accurately; therefore, insight into the scales being used is critical (Brewer et al., 2012). Various outcomes measures for upper limb function, pain and HRQoL were used in the studies reviewed (Brewer et al., 2012; De Weerd et al., 2012; Barreca et al., 2003). The researcher identified the following Measurement tools from the literature for the purpose of this study:

- Fugl-Meyer Assessment Upper Extremity (FMA-UE):
    - The FMA-UE is a good objective measurement tool and is valid and reliable. It does not require a great amount of equipment and is easy to execute (see Section 2.7.1).
- Wong-Baker FACES Pain Rating Scale (WBFPS):
    - Although other pain scales exist the researcher decided that a combination of the faces and the numerical numbers would make it easier for the participants to indicate their pain as a cognitive impairment as a complication post-stroke (see Section 2.7.2).
- Biodex Balance System (BBS):
    - The researcher aimed to identify another new objective measurement tool, which already is used for treatment purposes for postural stability, and apply the same principles. No other outcome measures are utilised specifically for shoulder stability specifically; they only measure components of shoulder stability (see Section 2.7.3).

- Short-Form 36 version 2 Questionnaire (SF-36v2):
    - The researcher wanted to use the SIS which is a stroke-specific scale, but after the pilot study, she identified that the some of the questions (especially with regard to interpretation) could not be answered effectively and consistently - no consistency was found with regard to participants' answers to similar questions. The researcher then decided to rather use the SF-36v2 (see Section 2.7.4).

These measurement tools will now be discussed in terms of each one's usefulness and the rationale for using it under specific circumstances.

2.7.1 Upper-limb function

Measurement tools used to assess upper-limb function:

(a) The Fugl-Meyer Assessment Upper Extremity (FMA-UE)

The Fugl-Meyer Assessment Upper Extremity (FMA-UE) (see Appendix A) is widely used for the measurement of functionality of the upper limb (Brewer et al., 2012; De Weerd et al., 2012; Barreca et al., 2003). The FMA-UE was developed for the assessment of sensorimotor function and is a disease-specific objective measurement for the assessment of the recovery of post-stroke hemiplegia (Gladstone et al., 2002). It is designed for the assessment of motor functioning (upper and lower limb), pain, balance, sensation and joint functioning (including ROM) in patients with post-stroke hemiplegia (Gladstone et al., 2002).

In this test summative scores ranging from 0–132 are generated for each of the seven domains tested in the assessment, namely upper-limb function, wrist function, hand function, coordination/speed, sensation, passive-joint motion and joint pain. The scores are based directly on the observation of performance and scaled on the basis of the ability to complete the item using a three-point ordinal scale where 0 = cannot perform, 1 = performs partially and 2 = performs fully.

The FMA-UE test is administered most frequently in stroke patients and has a high test–retest reliability and validity. Inter-rater and test–retest reliability of the FMA-UE items (including sub-scores from the items of the motor function, sensation and passive joint motion/joint pain) have been determined and a score of 0.95 is considered to be excellent (Platz et al., 2005).

Platz et al. (2005) tested the construct validity of the FMA-UE items using the Spearman correlation coefficient. Excellent correlations were found between the FMA-UE and the Action Research Arm Test (r = 0.93), the Box and Block Test (r = 0.92), and the Motricity Index (r = 0.86). The FMA-UE was compared to more general measures of impairment and activity limitation, including the Ashworth Spasticity Scale, the Hemispheric Stroke Scale and the modified Barthel Index and found valid (Platz et al., 2005).

(b) Action Research Arm Test (ARAT)

The Action Research Arm Test (ARAT) is an observer-rated, performance-based assessment of upper extremity function and dexterity (Hsueh et al., 2011; Van der Lee et al., 2002). The ARAT consists of 19 items designed to assess four areas of function, namely grasp (6 items), grip (4 items), pinch (6 items) and gross movement (3 items). Each question is scored on an ordinal scale ranging from 0 (no movement) to 3 (normal performance of the task). Within each subset, the first item is the most difficult and the second is the easiest. The remainder of the items are ordered by ascending difficulty. Successful completion of a particular task or item implies that subsequent, easier tasks also can be completed successfully. For each subset, the most difficult task is attempted first, and, if successful (i.e. 3 points are awarded), full points are awarded for that subsection. Scores range from 0–57, with lower scores indicating greater levels of impairment (Hsueh et al., 2011; Van der Lee et al., 2002). Advantages of the ARAT are that it is a relatively short and simple measure of upper-limb function that provides assessment of a variety of tasks over a range of complexity. The test covers most aspects of arm function, including proximal control and dexterity (Chanubol et al., 2012; Hsueh et al., 2011; Van der Lee et al., 2002). The ARAT can be used in the assessment of patients with moderate to severe

hemiparesis since the test allocates points for movement of the arm and hand even though the patient may not be able to pick up items required within the testing environment (Chanubol et al., 2012). An extensive collection of items and a specialized table are required for the test. Testing must be carried out in a formal setting. The test may be used without cost, but the original guidelines for administration contain limited detail (Yozbatiran et al., 2008).

The ARAT has shown good concurrent validity (test correlates with a previously validated measure), although other forms of validity have not been evaluated within the stroke population. Significant floor and ceiling effects have been identified (Van der Lee et al., 2002). The Action Research Arm (ARA) test is an assessment instrument for upper-limb function, of which the reliability and the validity also are considered to be good (Nijland et al., 2010; Koh, et al., 2006).

(c) Wolf Motor Function Test (WMFT)

The Wolf Motor-Function Test is used for the assessment of upper-limb function (Wolf et al., 2010; Wolf et al., 2006). The Wolf Motor-Function Test consists of seventeen (17) items or tasks. Tasks are arranged in order of complexity and progress from proximal to distal joint involvement. Tasks 1–6 involve joint segment movements and tasks 7–15 integrative functional movements and are assessed for performance time and quality of movement and function. While each task is timed excessive performance-time is typically truncated to 120 seconds. Summary score for performance time assessment is the median time recorded over all tasks (Morris et al., 2001). Functional scores are scored making use of a six-point scale, ranging from 0 (does not attempt with involved arm) to 5 (arm does participate and movement appears normal). Functional ability scale (FAS) scores are expressed as the mean of item scores (Morris et al., 2001). The patterns of movement range from simple to complex and may be used with individuals demonstrating a range of upper extremity motor function (Morris et al., 2001).

The test administration is fairly lengthy, requiring approximately 30-45 minutes (Bogard et al., 2009) and training is required in order to ensure reliable

administration. Validity and reliability research has been conducted for both versions of the S-WMFT (Chen et al., 2005); however, the S-WMFT in sub-acute stroke patients has been found to have a low level of responsiveness (not very sensitive to change) (Fu et al., 2012). The timed scores, as well as strength-based performance, may be affected by both gender and handedness (Wolf et al., 2006). In the streamlined versions of the test, Rasch analysis demonstrated no significant differential item functioning on the basis of sex, age or laterality of hemiparesis (Chen et al., 2005).

Reported levels of reliability are based on thorough training and practice sessions using videotaped assessment conducted until a maximum level of reliability is achieved (Morris et al. 2001). Scores provide an evaluation of upper-extremity function based on both performance time and quality of movement. The test itself is free for use, but costs may be incurred in the training of individuals who are to administer the test. Clinical feasibility also may be limited by the length of time required for testing and possible requirements for videotaping. There is little evidence regarding the reliability or validity of the scale when used via direct observation (Fritz et al., 2009; Lin et al., 2009).

2.7.2 Upper-limb pain

Measurement tools to determine the level of upper-limb pain include:

(a) Wong-Baker FACES Pain-Rating Scale (WBFPS)

The Wong-Baker FACES Pain-Rating Scale (WBFPS) (see Appendix B) is a self-report of pain that uses drawings of expressive faces (see Figure 2.2) as indicators of pain intensity ranging from “No hurt” (has a smile) to “Hurts worst” (has tears). The scale includes facial expressions, numbers and words. Participants give their own verbal response regarding the pain they experience. Scores may range between 0 and 10, with increments of two. The faces are not particular to any ethnic or cultural group and illustrate real human pain expressions, such as brow furrow and horizontal stretching of the mouth (Badr et al., 2006).



Figure 2.2: Wong-Baker FACES Pain Rating Scale
(Copied from Wong-Baker Foundation, 1983).

This tool boast excellent evidence of test–retest reliability of 79% (Badr et al., 2006; Miro & Huguet, 2004; Gharaibeh & Abu-Saad, 2002). Inter-rater and test-retest reliabilities of the WBFPRS were evaluated in various studies and were found to be excellent (Badr et al., 2006; Miro & Huguet, 2004; Gharaibeh & Abu-Saad, 2002). The WBFPRS has been used extensively in various countries and shows a 0.90 score for validity and a Cronbach's alpha of 0.93 (Badr et al., 2006; Miro & Huguet, 2004; Gharaibeh & Abu-Saad, 2002). A study by Khatri and Kalra (2012) found that the WBFPRS was more sensitive compared to the Visual Analogue Scale (VAS) in older children with acute pain.

(b) Verbal Numeric rating scale (VNRS)

In the numerical rating scale the patients verbally rate their pain score using a scale from 0 to 10 or by placing a mark on a line indicating their level of pain (Bourdel et al., 2014; Turk & Melzack, 2001). Zero indicates the absence of pain (no pain) and 10 represents the most intense pain possible. Numerical rating scales usually consist of a series of numbers ranging from, for example, 0 to 10. The ends of the scale are labelled to indicate "no pain" and the "worst pain possible." The patient chooses the number that best corresponds to the level of pain experienced. The Numerical Rating Pain Scale allows the healthcare provider to rate pain as mild, moderate or severe, which can indicate a potential disability level (Bourdel et al., 2014; Turk & Melzack, 2001). Numerical rating scales are valid and demonstrate positive and significant correlations with other measures of pain intensity (Richardson & Jones, 2009; Stinson et al., 2006). Turk & Melzack (2001) also have demonstrated sensitivity to treatments that are expected to have an impact on pain intensity. The NRS is

extremely easy to administer and score and therefore can be used with a greater variety of patients (e.g. older adults and patients with motor problems) than a VAS. It is also useful for telephone assessments. The simplicity of the measurement tool means that individuals identify better with it than with other tools.

The Brief Pain Inventory (Richardson & Jones, 2009) utilises a NRS but presents the numbers in ascending order with the endpoint descriptors near the 0 and the highest number of the scale a ten; it merely asks patients to circle the number that best represents their pain intensity.

(c) Visual Analogue Scale (VAS)

Visual analogue scales consist of a vertical or horizontal line, 10 cm in length, with end points labelled "no pain" and the "worst pain," or similar words. Patients are asked to rate their pain along the line that best represents the intensity of their pain. This distance between the no end and the mark provided by the patient is measured and this gives the pain intensity score (Bourdel et al., 2014; Turk & Melzack, 2001).

There is much evidence to support the validity of VAS for pain intensity. These scales demonstrate positive relations to other self-report measures of pain intensity and pain behaviour and are sensitive to treatment effects (Bourdel et al., 2014; Turk & Melzack, 2001). The VAS is also more sensitive than other measures especially those with a limited number of response categories because there are in fact 101 response levels (0 to 100mm) (Richardson & Jones, 2009; Gélinas et al., 2006). Some negative aspects of the VAS may be: Scoring is more time consuming and involves more steps (and more opportunity for error) than scoring for other measures of pain intensity; VAS requires the patient to have the ability to make a mark along the line or move the slide on a ruler; patients may find it difficult to understand, especially patients with cognitive problems; VAS requires careful explanations and reinforcement for the patients to use them accurately (Richardson & Jones, 2009).

(d) Verbal Rating Scale (VRS)

The Verbal Rating Scale consists of a list of adjectives describing different levels of pain intensity and patients respond on how they feel. Verbal rating scales consist of a series of words commonly used to describe pain (e.g., no pain, mild pain, moderate pain, severe pain). The patient reads the words and chooses the one that best describes the pain he or she is experiencing. A score (e.g., from 0–3) that is assigned to each word is then used to measure pain levels (Bourdel et al., 2014; Turk & Melzack, 2001). Verbal Rating Scales are easy to administer, score and comprehend (Richardson & Jones, 2009; Stinson et al., 2006). They are also valid and related positively and significantly to other measures of pain intensity (Bourdel et al., 2014; Turk & Melzack, 2001). It also consistently demonstrates sensitivity to treatments that are known to have an impact on pain intensity (Gélinas et al., 2006).

A negative aspect may be that it assumes equal intervals between the adjectives, even though it is extremely unlikely that it is perceived to be equal. That is, the interval between no pain and mild pain may be much smaller than that between moderate pain and severe pain, yet the interval is scored as if the difference were equivalent (Richardson & Jones, 2009; Gélinas et al., 2006). Other aspects may be that the patients are not familiar with the terms before they select one that most closely resembles their pain and for a four point scale this is not that problematic, but it may be time consuming; patients may not find a descriptor that accurately describes their perceived pain intensity; in patients who are illiterate, they are less reliable than other pain intensity measures (Stinson et al., 2006).

2.7.3 Assessment of shoulder stability

For the assessment of shoulder stability, the following may be used:

(a) Biodex Balance System (BBS)

The Biodex Balance System (BBS) (see Appendix C) is a multi-axial system that is used to objectively measure balance and postural stability on a stable and unstable

base of support (Pereira et al., 2008; Cachupe et al., 2001). Thus the BBS is an objective measuring tool of an individual's ability to stabilise the involved joint (Karimi et al., 2008). The BBS (see Figure 2.3) consists of a circular platform that is able to move in different axis (anterior–posterior and medial–lateral) simultaneously, while adjusting stability over 12 levels (level 12 most stable = static; level 0 most unstable). Various measures of postural stability that may be determined by the BBS and it can measure the degree of tilt of each axis during dynamic movements (Pereira et al., 2008; Cachupe et al., 2001).



Figure 2.3: Biodex Balance System
(Copied from Biodex Medical Systems, Inc., 2011).

The BBS provides a stability index (SI) value which represents the displacement from a level platform position (0.0) in all different motions, namely anterior–posterior (Ant/Post), medial–lateral (Med/Lat) and overall (O/A) (Hinman, 2000). The overall SI takes into account the displacement from the level platform position in the anterior–posterior (sagittal plane) and the medial–lateral (frontal plane). A high SI is associated with an unstable posture and indicates decreased shoulder girdle stability, while a low SI (closer to 0.0) is associated with a stable posture and, thus, indicates less joint instability (Hinman, 2000). The SI is calculated by the BBS using standardised formulas for the different motions of movement (Figure 2.4) (Pereira et al., 2008; Cachupe et al., 2001).

$$APSI = \sqrt{\frac{\sum(0-Y)^2}{number\ \ of\ \ samples}}$$

$$MLSI = \sqrt{\frac{\sum(0-x)^2}{number\ \ of\ \ samples}}$$

$$OSI = \sqrt{\frac{\sum(0-Y)^2 + \sum(0-X)^2}{number\ \ of\ \ samples}}$$

Figure 2.4: Formulas for the calculation of SI
(Copied from Biodex Medical Systems, Inc., 2011).

During static and dynamic stability exercises, the BBS can provide visual feedback of patients' ability to control their centre of gravity and can assess their neuromuscular control in closed-chain and multiplane exercises. Apart from assessing either static and/or dynamic balance, the BBS can also compare the involvement of bilateral effects of affected limbs (Ballard, 2005; Cachupe et al., 2001).

The BBS can be used in patients with neurological conditions such as stroke, Parkinson's disease, multiple sclerosis and any head or spinal cord injury resulting in a loss of balance or ambulatory motor skills (Cachupe et al., 2001). During the rehabilitation of these patients the BBS is used to restore the affected motor skills by means of retraining of new neural pathways, proprioception, and the maintenance of positioning, balance and weight transfer (Ballard, 2005; Cachupe et al., 2001). The BBS is effective because it provides immediate feedback and makes it easier for the patient to relate to and repeat the movements. It also renders objective progress data and documents treatment sessions (Ballard, 2005; Cachupe et al., 2001).

Three major advantages of the BBS are described by Cachupe et al. (2001). First, the BBS allows the performance of scapular stabilisation drills, during which, patients use their arms to manipulate the platform. Second, the BBS provides instant biofeedback, making it easy for patients to understand and repeat the motions. Third, the BBS creates a safe, controlled environment, allowing patients to progress from

non-weight bearing to weight bearing. The progress is produced on the screen and is useful in assisting to monitor the movement (Cachupe et al., 2001).

Using BBS on the upper limb, as required for this study, needs more attention. According to literature, the BBS is used to assess balance and postural control (Aydoğ et al., 2006). Retraining balance is complex involving visual, vestibular and neuromuscular control. Body position and smooth functional movement patterns result from these coordinated actions together with integration of graded ankle, knee and hip movements along the kinetic chain. To be able to maintain balance the body makes use of different movement strategies, for example, ankle, hip and stepping strategies. These strategies allow the lower limb (hip or ankle) to adjust balance in response to movement. In the hip strategy, activation of muscles occurs from the trunk downwards, or proximal to distal. Lower limbs movements require dynamic stability of the entire body (Aydoğ et al., 2006; Bouisset et al., 2006; Baldwin et al., 2004).

The BBS is a sensitive test of balance performance as it makes use of a dynamic tilting platform, activating the neuromuscular control as well as the visual and vestibular components. If balance is interrupted, effective motor activity is required to be able to return the centre of mass within the base of support. Effective motor activity consists of optimal muscle strength and an intact neuromuscular system. Thus, retraining optimal balance requires optimal postural and proximal stability.

During stance/ bilateral weight bearing the BBS assesses to what degree the participant is able to maintain the centre of gravity in the lower limbs (Aydoğ et al., 2006; Baldwin et al., 2004). During the testing the participant steps with both feet onto an indicated place on the platform of the BSS and assumes a comfortable position while maintaining a slight flexion in the knees (15°) and looks straight ahead. First, it starts in a static plane where the participant is asked to maintain optimal balance and maintain equal weight bearing over both sides. This measures the stability index. The stability index represents the variance of platform displacement in degrees of the level. A high number (measure on BBS) indicates much movement, implying that the participant is struggling to maintain his/her balance. Bilateral

(between right and left) comparisons and differences between lower limbs immediately may be documented. As soon as the participant is able to control the platform, the platform is unlocked allowing different degrees of movement making it more difficult to maintain the centre of gravity. With a great variance it indicates a poor balance and postural stability. Scores higher than normative values suggest further assessment for lower extremity strength, proprioception and vestibular or visual deficiencies, thus also indicating decrease stability (Aydoğ et al., 2006; Baldwin et al., 2004).

According to the above-mentioned employment of the BBS as measurement tool for the lower limbs, the researcher applied the BBS to measure weight bearing of the upper limb, keeping in mind that a difference between left and right might be detected. The participant should be able of equal weight bearing (centre of gravity) and a lower score (stability index), indicating better balance and postural stability. A lower score thus would indicate more stability of the surrounding and weight-bearing joints.

The BBS has an alternative application for closed-chain scapular stabilisation exercises (Blackburn & Guido, 2000). The BBS targets the somatosensory and neuromuscular aspects of balance and stability in order to improve and/or maintain control of the centre of gravity over the patient's base of support. The improvement or maintenance of this control depends upon the neuromuscular mechanisms of proprioception, strength and power of the individual (Cachupe et al., 2001).

For the accurate assessment of dynamic postural stability, the outcomes measures must be both valid and reliable but, according to Pickerill and Harter (2011), the reliability of many of the outcomes measures have not been confirmed. However In a study conducted on the reliability of the BBS, researchers measured the reliability of dynamic balance assessments on 20 active male and female individuals. The results across a series of eight trials showed that the BBS produced reliable measures (Cachupe et al., 2001). Kovaleski et al. (2009) also found highly reliable results with values ranging from 0.90 to 0.96.

From literature it seems that limited research has been done on the BBS and its reliability and validity when used on the upper limb. The BBS has been used mostly for balance training in a standing position (Pereira et al., 2008; Cachupe et al., 2001).

(b) Range of motion

The shoulder is normally is the most unstable joint in the body; it can demonstrate significant gleno-humeral translation (motion) (Brukner et al., 2012; Martin & Fish, 2008). The unaffected limb also should be examined for comparison with the affected side. Abnormal tone is a post-stroke complication and may interfere with the normal scapula-humeral rhythm, reduced movement and increased restriction as well as a decrease in range of motion (specifically, external rotation) (Adey-Wakeling et al., 2013; Sackley et al., 2008) (also see Section 2.5).

Active range of motion performed by the patient typically is assessed first, and may be affected by both pain and motor function. Active and passive ranges should be assessed. Movements include forward flexion, extension, internal/external rotation, and abduction/adduction. Normal motion for forward flexion is considered to be 0° to 170-180°, while normal extension is said to be 60°. For internal and external rotation it was noted that the arm should be abducted to 90° for an accurate measurement. Normal internal rotation is said to be 90°, while normal external rotation is more or less 60-70°. These values may vary with regard to age, pathology and sporting/recreational activities. For adduction, the assessment is normally limited due to the trunk, but typically 30° is considered normal. Abduction motion may range from 0° to 180° (Brukner et al., 2012; Martin & Fish, 2008).

It is also important to note the normal scapula-humeral rhythm/motion. Shoulder abduction involves the gleno-humeral joint and the scapula-thoracic articulation. Gleno-humeral motion may be isolated by holding the patient's scapula with one hand while the patient abducts the arm. The first 20 to 30° of abduction should not require scapula-thoracic motion. With the arm internally rotated (palm down), abduction continues to 120°. Beyond 120°, full abduction is possible only when the humerus is externally rotated (palm up) Apley's scratch test. The patient should

attempt to touch the opposite scapula to test the range of motion of the shoulder, while “hand behind head” assesses abduction and external rotation and “hand behind back” is used to assess adduction and internal rotation (Brukner et al., 2012; Martin & Fish, 2008).

(c) Sulcus sign

Subluxation of the Gleno-humeral joint due to hypotonicity in the upper limb may by a complication post-stroke (see Section 2.5). It may be the result of the weight of the upper limb stretching and straining the joint capsule (Martin & Fish, 2008). To assess shoulder subluxation it is important to look for the Sulcus sign. With the patient's arm in a neutral position, the assessor pulls downward on the elbow or wrist while observing the shoulder area for a sulcus or depression lateral or inferior to the acromion. The presence of a depression indicates inferior translation of the humerus and suggests inferior gleno-humeral instability. Normally in stroke patients the sulcus can be observed (without pulling the arm down) with the muscle atrophy (Brukner et al., 2012; Martin & Fish, 2008).

(d) Electromyography (EMG)

Electromyography (EMG) is a diagnostic procedure to assess the health of muscles and the nerve cells that control them (motor neurons). Motor neurons transmit electrical signals that cause muscles to contract. An EMG translates these signals into graphs, sounds or numerical values that a specialist interprets. An EMG uses small electrodes to transmit or detect electrical signals. During a needle EMG, a needle electrode inserted directly into a muscle records the electrical activity in that muscle. A nerve conduction study, another part of an EMG, uses electrodes taped to the skin (surface electrodes) to measure the speed and strength of signals travelling between two or more points. EMG results can reveal nerve dysfunction, muscle dysfunction or problems with nerve-to-muscle signal transmission (Rodrigues et al., 2006; Morris et al., 2003).

2.7.4 HRQoL

To assess Health-related quality of life, the following may be used:

(a) Short-Form 36 version 2 Questionnaire (SF-36v2)

The Short-Form 36 version 2 Questionnaire (SF-36v2) (see Appendix D) is a widely used questionnaire to measure HRQoL from the patient's point of view for a variety of medical conditions. It is a brief, self-administered questionnaire that generates scores across eight dimensions of health. The eight multi-item scales are physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. The eight health domains can be summarised in two components, namely the physical component summary (PCS) and the mental component summary (MCS) (Atif et al., 2013; Demet et al., 2008).

The scores range from 0 (lowest or worst possible level of functioning) to 100 (highest or best possible level of functioning). A lower score is representative of weaker experience of HRQoL while a higher score represents better experience of HRQoL (Demet et al., 2008; Ware, 2000).

The SF-36v2 is a valid and reliable instrument to assess HRQoL and the reliability of the eight scales and two summary measures have been estimated to be between 80% and 85%, with a reliability coefficient of 0.93 for the Mental Health Scale (Atif et al., 2013). Social factors such as type of employment, income and educational level may influence the outcome of the SF-36v2. The SF-36 is a reliable and valid measure for determining HRQoL in stroke patients (Demet et al., 2008; Bjelland, 2002; Ware, 2000). Comparisons to other general population studies further indicate that the SF-36v2 is suitable for telephone administration (Atif et al., 2013).

(b) European Quality of life (EQ-5D-5L)

The European Quality of life (EQ-5D-3L) is a health-related quality of life instrument that provides a simple, descriptive health profile. It has been translated into more than one hundred languages worldwide (Pattanaphesaj & Thavorncharoensap, 2015; Van Hout et al., 2012). It is very simple and can be completed by the patient. The EQ-5D comprises two parts: a simple descriptive profile that may be converted into a single summary index (the EQ-5D index), and a visual analogue scale (VAS) (Pattanaphesaj & Thavorncharoensap, 2015; Van Hout et al., 2012).

The descriptive system is composed of five dimensions. The dimensions are mobility; self-care; usual activities; pain/discomfort; and anxiety/ depression. Each dimension has five levels of perceived problems (no problems, slight problems, moderate problems, severe problems, and extreme problems), where level 1 indicates no problem and level 5 indicates extreme problems which can tally to 243. During the VAS, the participants rate their health on a 20-centimetre vertical scale. The scale ranges from 0 to 100, where 0 means the worst possible health that the respondent can imagine and 100 indicates the best possible health in the respondent's viewpoint (Pattanaphesaj & Thavorncharoensap, 2015). The ceiling of the EQ-5D was defined as the proportion of respondents scoring no problems on any of the five dimensions, that is, the proportion of respondents scoring 11111 (Janssen et al., 2013; Van Hout et al., 2012).

Studies have found that it is a valid and reliable instrument and showed good face validity and test-retest reliability (Janssen et al., 2013; Van Hout et al., 2012). The EQ-5D-5L has been validated in a diverse patient population in six countries, including eight patient groups with chronic conditions (cardiovascular disease, respiratory disease, depression, diabetes, liver disease, personality disorders, arthritis, stroke) and a student cohort (Janssen et al., 2013; Van Hout et al., 2012).

Convergent validity was evaluated by correlations between the EQ-5D and SF-36v2 dimensions. Both the 3L and 5L presented an acceptable degree of association and a similar correlation pattern with the SF-36v2 in some pairs of dimensions, that is

mobility versus physical functioning; pain/discomfort versus bodily pain; and anxiety/depression versus mental health (Pattanaphesaj & Thavorncharoensap, 2015; Janssen et al., 2013; Van Hout et al., 2012). A cross-sectional multi country study (Janssen et al., 2013) reported evidence of the feasibility and validity of the EQ-5D-5L in a variety of conditions, showing a low level of missing values, establishing known groups validity and showing improved discriminatory power and improved convergent validity in comparison with EQ-5D-3L Pattanaphesaj and Thavorncharoensap (2015) and Van Hout et al. (2012) came to similar conclusions.

(c) Stroke Impact Scale, (SIS)

The Stroke Impact scale is a stroke-specific scale that assesses health status (physical as well as quality of life) and reports the patient's outcome. The SIS comprimises 59 items and assesses eight domains (strength, hand function, ADL/instrumental ADL, mobility, communication, emotion, memory, thinking and social participation) (Huang et al., 2010; Lin et al., 2010; Carod-Artal et al., 2009; Gurcay, et al., 2009). The participant has to answer with either the number or the text associated with the number (e.g., "5" or "Not difficult at all"; "1" or "could not do at all") for each of the questions. Summative scores (ranging from 0-100) are generated for each of the eight domains (Strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking and participation/role function) (Huang et al., 2010; Lin et al., 2010; Carod-Artal et al., 2009; Gurcay, et al., 2009).

It is recommended that patients score at least 16 on the Mini-Mental Exam. The SIS can be mail administered, completed by proxy, completed by proxy by mailed administration, or be administered by telephone. The SIS should be used with caution in individuals with mild impairment as the items in the communication, memory, and emotion domains are considered easy and only capture limitation in most impaired individuals. The SIS would be appropriate if the patient has spent time living in the community post-stroke as many items relate to living at home (Huang et al., 2010; Gurcay, et al., 2009).

The interclass correlation coefficients for test-retest reliability of SIS domains ranged from 0.70 to 0.92, except for the emotion domain (0.57). When the domains were compared with established outcome measures, the correlations were moderate to strong (0.44 to 0.84). The participation domain was most strongly associated with SF-36 social role function. SIS domains are responsive to change due to ongoing recovery. Responsiveness to change is affected by stroke severity and time since stroke. The SIS is a stroke-specific outcome measure and is reliable, valid, and sensitive to change (Doyle et al., 2007; Edwards & O'Connell, 2003).

(d) Stroke and Aphasia Quality of Life Scale-39 (SAQOL-39)

SAQOL is a self-report questionnaire that comprises the 49 items of the SS-QOL (modified to be communicatively accessible to people with aphasia) and four additional items to increase its content validity. The 53 items is divided in the twelve domains of energy, family roles, language, mobility, mood, personality, self-care, social roles, thinking, upper extremity (UE) function, vision, and work/productivity. The domains are scored separately, and a total score is also provided (Lima et al., 2008; Muus et al., 2007). The SAQOL has two response formats, both based on a 5-point scale: 1= could not do it at all to 5 = no trouble at all and 1 = definitely yes to 5 = definitely no. Overall and subdomain scores may range from 1 to 5; the overall SAQOL score is calculated by summing across the items and dividing by the number of items; subdomain scores are calculated the same way. The SAQOL-39 is a psychometrically robust measure that can be used to assess HRQL in most stroke survivors, including people with aphasia, in clinical practice, and in research (Lima et al., 2008; Muus et al., 2007; Hilari et al., 2003).

Of the stroke-specific scales, the Stroke-Specific Quality of Life Scale (SS-QOL), in addition to the Stroke Impact Scale version 3.0 (SIS 3.0), is the most comprehensive and frequently used patient-reported outcome measure (Lima et al., 2008; Muus et al., 2007; Hilari et al., 2003). The SAQOL-39 is an acceptable, reliable, and valid measure of HRQL in people with long-term aphasia. The SAQOL-39 demonstrates good acceptability, internal consistency (Cronbach's alpha=0.74 to 0.94), test-retest reliability (intra-class correlation coefficient=0.89 to 0.98), and construct validity

(corrected domain-total correlations, r=0.38 to 0.58; convergent, r=0.55 to 0.67; discriminant, r=0.02 to 0.27 validity) (Hilari et al., 2003).

2.8 Conclusion

Notwithstanding the progress being made in the acute management of stroke, the prevalence of stroke-related disability is increasing worldwide. Post-stroke disability has a severe impact on patients' HRQoL and ability to live independently, as well as on their families, healthcare systems and the economy. Functional rehabilitation is crucial in reducing disability after stroke and should aim to improve upper limb function. Evidence of the effects of individual treatment modalities is found throughout the literature. Yet, to date, studies have largely have been aimed at clearly identifying treatment modalities to improve shoulder girdle stability, to identify the impact of these modalities on shoulder girdle stability, and to identify the effect of these modalities on upper limb function post-stroke.

There is a constant need to explore and introduce new modalities or therapies to complement or enhance current rehabilitation, but questions remain with regard to the functional recovery, the clinical effect, long-term safety and socio-economic impact of many of these interventions. Further research could answer these questions and new techniques could create great expectations for the future of stroke rehabilitation. This study aims to answer some of the questions with regard to the use of the BBS in neurological rehabilitation of the upper limb as limited research has been done in this regard. The BBS has been used mostly for balance training in a standing position, but this study aims to determine its effect on the hemiplegic upper limb.

This chapter brought the reader an in-depth synthesis of the literature regarding shoulder girdle stability, upper-limb function, upper-limb pain, HRQoL and factors affecting shoulder girdle stability. The next chapter (Chapter 3) explores the methodological process that was followed in order to conduct this study and answer the research aim and objectives.

CHAPTER 3

3. RESEARCH METHODOLOGY

This chapter describes the research methodology applied in the study reported here and covers aspects such as the study design, variables, hypothesis tested and the sample selected. Furthermore, it gives a detailed description of the data collection and the methods applied for data analysis. The ethical considerations and possible methodological errors related to the study are also presented in the chapter.

3.1 Study procedure

An outline of the study procedure and the sequence in which the study was executed is provided in Figure 3.1 as background to the research methodology discussed in this chapter. Each of these aspects will be outlined in detail in the rest of this chapter.

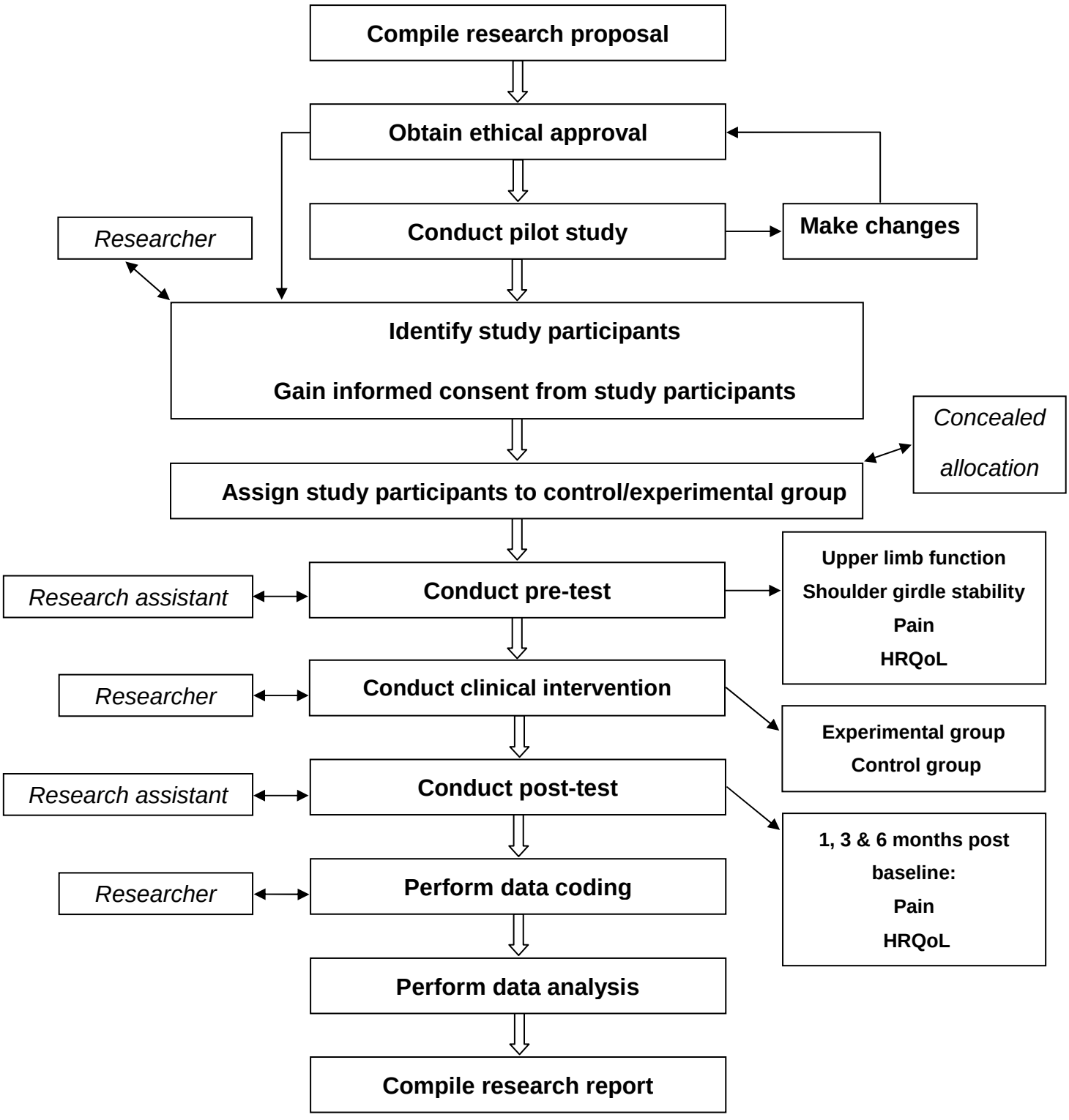


Figure 3.1: Flow diagram of study procedure

3.2 Study design

The study utilised a quantitative longitudinal randomised control trial (RCT) design because it tested the participants over a time period of six months. In quantitative research the aim is to determine the relationship between an independent variable and another dependent or outcome variable in a population to measure outcomes from the study (Yitschaky et al., 2011; Sapoka et al., 2010).

Randomised control trials are considered to be the most reliable form of scientific evidence as it reduces spurious causality and bias, can provide strong evidence for causality in relation to temporality and control for unknown "confounders", it allows for comparison of multiple outcomes, it can fulfil the basic assumption of statistical hypothesis tests, and these results may be combined in systematic reviews conducted on evidence-based practice (Rajagopalan et al., 2013; Yitschaky et al., 2011; Johnston et al., 2006; Rothwell, 2005).

Disadvantages are limitations of external validity, namely it may take a long time, it may be very complex and expensive, subjects often are a highly selected group (selected for willingness to comply with treatment regimen) and volunteers may differ from population of interest, not suitable for rare outcomes, not suitable for outcomes requiring prolonged or extensive follow-up, adherence/withdrawal issues, narrowing of the studied question, sometimes impossible or impractical to conduct and there may be a conflict of interest. Factors that influence the external validity include the following; where the study was performed, characteristics of the patients, the study procedures, the outcome measures used as well as the incomplete reporting of adverse effects of interventions (Rajagopalan et al., 2013; Sullivan, 2011; Yitschaky et al., 2011; Sapoka et al., 2010; Johnston et al., 2006; Rothwell, 2005).

The participants were allocated randomly to the experimental and control groups for the particular intervention, during which, the researcher administered all the interventions on the BBS and the researcher assistant completed the assessments of the participants. This is the best type of study design to determine whether a treatment is effective. Bias is also less likely when subjects are assigned randomly to

such groups and when the participants and researchers are blind to the allocation of the groups (Sullivan, 2011; Yitschaky et al., 2011; Sapoka et al., 2010).

The study was single blinded, as only the research assistant doing the pre- and post-testing was blinded. The research assistant was unaware of the group allocation of the participants, as well as of its effect on the intervention. This was done to avoid the research assistant being influenced or biased by this knowledge during testing (Yitschaky et al., 2011; Sapoka et al., 2010).

Both groups were pre- and post-tested with follow-up assessments (at one, three and six month/s) post-baseline.

3.3 Ethical considerations

Ethical clearance for this study was obtained from the University of the Witwatersrand Ethics Committee under Ethical Clearance number M130405 (Appendix E), as well as from the University of the Free State under Ethical Clearance number 79/2013 (Appendix F).

Permission was obtained from the Manager of Life Rehabilitation Unit (Pasteur Hospital) in Bloemfontein prior to the commencement of the study (Appendix G).

All participants gave written, informed consent to have their data included in the study (Appendix H). Information was made available to the participants in English and Afrikaans, according to their language of choice. Patients who refused to participate were not prejudiced in any way. Data that were collected were kept safe and were used only for the purposes of the research. Electronic data also were kept safe in a password-protected document on the storage CD. Participants' names were not recorded on the data collection sheets so as to maintain anonymity and each participant was assigned a code number at the beginning of the study.

All data were treated as confidential and no results were linked to the participants' names. Only the researcher was able to identify participants. The informed consent

letters were kept separately from the pre- and post-test data. Only the study participants' numbers appeared on the pre- and post-test data forms.

The researcher alone dealt with all the data, informed consent forms and administrative documentation.

3.4 Study participants

The study population included all stroke patients admitted to the Life Rehabilitation Unit (Pasteur Hospital) in Bloemfontein during the period from 10 January 2014 to 31 March 2015. A total of 129 patients were admitted with an average of eight per month for this period.

3.4.1 Research setting

Participants were recruited from the Life Rehabilitation Unit (Pasteur Hospital). The Life Rehabilitation Unit (Pasteur Hospital) is a 42-bed private hospital which offers acute interdisciplinary rehabilitation for patients with neurological conditions including stroke, traumatic brain injuries, tumours and other disabling injuries or conditions. Patients from all over South Africa are admitted, but they are primarily from the Free State, Northern and Eastern Cape. The patients receive a minimum of three and a half hours intensive therapy per day consisting of physiotherapy, occupational therapy, speech therapy, social work and neuropsychology therapy. The individualised therapy programmes consists among other things, of neuromuscular re-education, therapeutic exercises, mobilisation of joints, balance retraining, re-education of gait, task-specific training, retraining of ADL, and improvement of problem-solving and motor learning skills. Programmes aim to facilitate optimal functional independence and are individualised according to each patient's needs (Life Healthcare, 2015). The researcher is conversant in English and Afrikaans all the participants reside in the Free State and Eastern Cape and also were conversant in English and Afrikaans. The participants were addressed in the language of preference thus either in English or Afrikaans.

3.4.2 Sample size and selection

Sampling is a very important aspect of a study, as the sample should be representative of the population in which the researcher is interested. Therefore the sample must comprise the elements of the population (Strydom & Venter, 2002). It is generally stated in literature that the larger the population, the smaller the sample size needs to be, but the greater the probability of sample error, the larger the sample size should be. Regarding the selection of the sample, Strydom and Venter (2002) affirm that random sampling is regarded by most methodologists as the only technique available that will ensure representativeness of the population from which it is drawn. In this study purposive sampling was done according to specific inclusion and exclusion criteria (Strydom & Delport, 2002) and the participants selected were assigned randomly to a control group and an intervention group respectively.

3.4.2.1 Sample size

In this study the aim was for a total sample size of 16 hemiplegic patients with stroke and impaired upper limb function. A total of 17 participants were included in the main study after screening (ten in the experimental group and seven in the control group).
A sample size of 16 participants has 90% power to detect a difference in means of 0.2 assuming a standard deviation of 0.1 using shoulder girdle stability as the main outcomes measure, allowing for a 10% non-compliance and taking into account a drop out (loss to follow-up) of 10% with significance set at 5% ($p \leq 0.05$) (Aberson, 2010).

3.4.2.2 Sample selection

The researcher screened all the patients admitted with stroke for inclusion into the study. The inclusion and exclusion criteria for the study were as follows:

(a) Inclusion criteria:

Participants were included in study if they met the following criteria:

- were either male or female stroke patients,
- had a stroke, resulting in hemiplegia and/or shoulder instability, and
- were between the ages of 18 and 85 years.

(b) Exclusion criteria

Participants were excluded due to the following conditions:

- being medically unstable:
    - if the doctor advised that the patient is not medically stable to continue with rehabilitation in the gym and can only tolerate the minimum sessions,
- experiencing extreme shoulder instability and/or pain:
    - if there was a positive sulcus sign, and/or
    - if the patient experience severe pain with shoulder movement in range of motion less than 90 degrees of shoulder flexion and abduction,
- having a severe cognitive impairment as measured with the FIM and mini-mental cognitive tests, that is:
    - an average FIM score of less than three for the cognitive group as documented in the screening information, and
    - a screening score of less than 15 (out of 30) for the mini-mental cognitive screening tool;
- having difficulty understanding instructions during the pre-screening interview,
- having a severe visual impairment - not being able to read a font size of Arial 12, and
- having severe aphasia and being unable to answer questions.

The rationale for the exclusion criteria needs elucidation.

Cognitive impairment might have had the following effects:

- The participants' ability to control their shoulder girdle (motor planning and sequencing of movement) would be limited, as well as their ability to adjust to the platform of the BBS, and their ability to follow rehabilitation instructions. For purposes of the study the participants had to maintain and adjust their position on the BBS.

The participants' ability to answer the questions in the HRQoL measurement questionnaire might have been compromised. Participants were required to answer the questions posed in the HRQoL questionnaire verbally (see Sections 2.5, 2.6 and 3.5). Therefore, if participants presented with either receptive or expressive aphasia, they had to be excluded from the study. The assessment of the HRQoL was done by means of a structured interview at baseline and one-month follow-up post-baseline and completed telephonically at three- and six-months follow-up post-baseline.

Participants were screened for visual impairments (as defined for this study, see Sections 2.7 and 3.5). Participants were required to follow a small dot on the BBS screen and if they were unable to follow the dot on the screen due to visual impairment with or without their spectacles, they had to be excluded. If patients presented with visual impairments they would have been unable to follow and track their movement on the screen and to adjust to maintain the correct position on the BBS.

3.4.2.3 Sampling method

Two groups of participants were involved in the study, namely an experimental and a control group. The experimental group was subjected to an intervention that they would not have been part of their rehabilitation plan, if it had not been for the research, whereas the control group served as a basis of comparison and did not receive any additional interventions. The participants were assigned randomly to one of the two groups using computer-generated random numbers through concealed allocation. This was done by a third party who was not involved in the assessment or clinical interventions of the participants. A pre-generated computerised list was used

for assigning participants to the different groups; this technique was chosen to prevent selection bias. Allocation concealment prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a specific intervention group (Yitschaky et al., 2011; Sapoka et al., 2010).

3.5 Procedure of data collection

Data were collected by means of measurement tools and a questionnaire. A pilot study was conducted before the researcher embarked on the main study.

3.5.1 Pilot study

Before data collection for the study started, a pilot study was performed. The pilot study served to orientate the researcher and the research assistant with regard to the project, establish the time taken to perform tasks with each individual patient, check the feasibility of the intervention, and determine the reliability of the outcomes measures and the screening procedure. The pilot study also tested whether participants would be able to maintain the test position on the BBS for at least five minutes, because this was the minimum time needed to complete one level of testing on the BBS.

The pilot study participants were five stroke patients admitted to the Life Rehabilitation Unit (Pasteur Hospital) in Bloemfontein who presented with impaired shoulder girdle stability and decreased upper-limb function and who met the inclusion criteria for the study.

The same study procedure was followed as for the main study (see Figure 3.2). After having beenadmitted the participants were screened by the researcher for possible inclusion according to the inclusion and exclusion criteria (see 3.4.1.2). The participants' demographic details were captured after informed consent had been given and it had been established that they complied with the inclusion criteria. The participants were pre-tested, after which they received the clinical intervention on the BBS. This intervention involved nine treatments distributed over a three-week period.

All the participants were post-tested on the BBS after one month only. The following flow diagram (Figure 3.2) is a representation of the procedures of the pilot study.

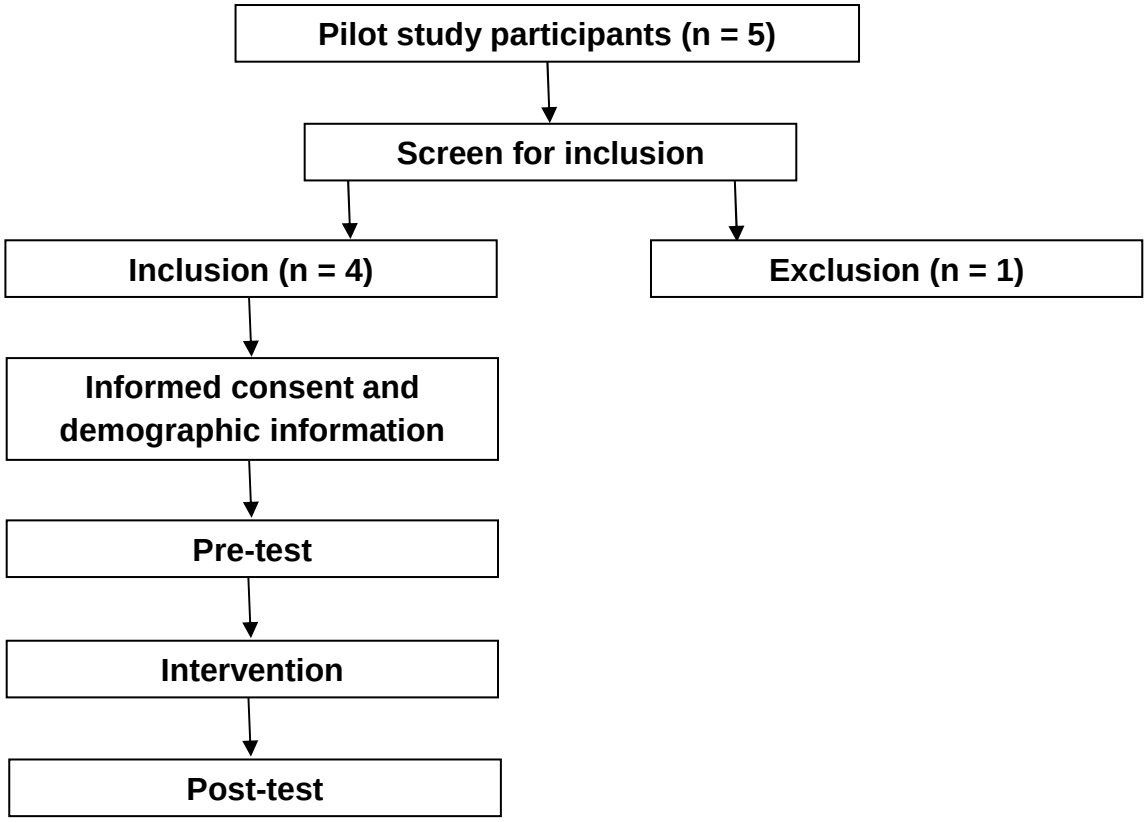


Figure 3.2: Flow diagram of the pilot study

After the pilot study some changes were made. An additional cognitive screening tool (mini-mental) was added to the screening procedure to ensure that the participants would be able to understand and respond in a more reliable manner to the HRQoL questionnaires. Some of the questions required the participants to respond on a higher cognitive level (for example, their emotional state) and were not aimed at their basic needs only (for example, mobility or ADL). The data of the pilot study were not included for analysis in the main study due to these changes.

3.5.2 Main study

Permission was obtained from the manager of Life Rehabilitation Unit (Pasteur Hospital) in Bloemfontein prior to the pilot and the main study (see Appendix G).

The researcher and the research assistant were responsible for data collection: the researcher was responsible for the screening, demographic information, informed consent as well as for the intervention and the research assistant for the assessments. The researcher and the research assistant both are neurodevelopmental therapy (NDT) trained and both had 12 years clinical experience in neurological rehabilitation. The researcher and research assistant have been working together for five years prior to conducting the study.

The researcher identified all the stroke patients admitted during the period from 10 January 2014 to 31 March 2015 at Life Rehabilitation unit (Pasteur Hospital). The researcher consulted with the rehabilitation admission consultant daily to confirm the daily admissions and the planned admissions for the following week.

All possible participants were screened for eligibility for inclusion in the study using the screening checklist developed specifically for the study (Appendix I). Screened participants who complied with the criteria for inclusion in the study were required to give informed consent (Appendix H) to partake in the study. Consent was sought after the patients had been provided with all the relevant information regarding the study and the study procedure had been explained to them (all relevant information was given and time was allocated for questions).

After consent had been given the participants' demographic details were captured on the demographic information sheet (Appendix J) by the researcher. The demographic details were obtained from the participants' patient files, the social worker, as well as the participant after the information session and the informed consent had been obtained. An appointment was scheduled for pre-testing by the research assistant.
The participants were then assigned randomly to one of two groups, using a computer program that generated random numbers with concealed allocation. Allocation was done by a third person who was not involved in the assessment or the clinical intervention of the participants.

All the participants were assessed by the research assistant according to the outcomes measures (explained in Section 3.6) during the scheduled appointment

time. Various studies done from 2000 to 2014 reported that the assessments were done by a blinded assessor - for the purpose of this study the research assistant was the blinded assessor (Corbetta et al., 2015; Lohse et al., 2014; Norouzi-Gheidari et al., 2012; Winter et al., 2011; Subramanian et al., 2010; Latimer et al., 2009) (Appendix L). The duration of the interventions also was no longer than the assessments, which was one reason why the researcher did the intervention. Another reason was that the BBS is a fairly new modality and the researcher wanted to monitor the safety of the study participants by doing the interventions. The research assistant first assessed HRQoL by using the SF-36v2, then assessed pain, using the WBFPRS, then upper-limb function, using the FMA-UE and, finally shoulders stability on the BBS.

Both the control and experimental groups continued with the standard therapy programme as discussed earlier (Section 3.4). All the testing and interventions were done after the completion of their normal therapy and as scheduled and arranged by the researcher.

The control group received no additional clinical intervention like the experimental group did, apart from their standardised therapy programme and was only pre- and post-tested on the scheduled times. The control group continued with their individualised, standard therapy programmes. The experimental group continued with their individualised, standard therapy programmes, but also received additional shoulder stability training using the BBS.

The intervention programme was designed taking into consideration the FITT principles with regard to frequency, intensity, time as well as the type of exercise (Billinger et al., 2015). The clinical intervention on the BBS consisted of nine treatments distributed over a three-week period. During consultation with the rehabilitation admission consultant of the Life Rehabilitation unit (Pasteur Hospital) it was determined that the medical aid schemes allowed, on average, 28 days for stroke rehabilitation. This correlated with a study done by Rouillard et al. (2012) that determined that patients be admitted for 30 days. Clinical intervention sessions were spread evenly over the 28 days with one day rest; thus only three clinical

interventions were done per week (Stroke Engine Module, 2012; Gordon et al., 2004). If participants missed two consecutive interventions, they were excluded from the study.

Each treatment lasted between 15 and 20 minutes, depending on the time taken to rest between exercises. Studies done by Billinger et al. (2015) and Gordon et al. (2004) suggested shorter therapy sessions post-stroke, starting with 10 minutes of continuous exercise. With each treatment the participant was placed in the correct predetermined position on the BBS. Weight bearing over the hemiplegic side is an effective treatment modality that does not require fine motor control in order for patients with severe weakness and loss of motor control to learn to support body weight (Lang et al., 2012; Davies, 2000) (also see Section 2.6.1). Weight bearing may be done by placing the forearms on a table as weight bearing on extended upper limbs is more difficult and requires more control (Lang et al., 2012; Davies, 2000). In this study the participant was placed on a high–low Bobath plinth in puppy position, that is prone, with elbows placed on the BBS in a 90° angle, shoulders perpendicular to the trunk (see Figure 3.3). The screen of the BBS was adjusted so that the participant was able to see the screen for visual feedback. The researcher ensured that the participant was in the correct posture to achieve optimal stability and safety.

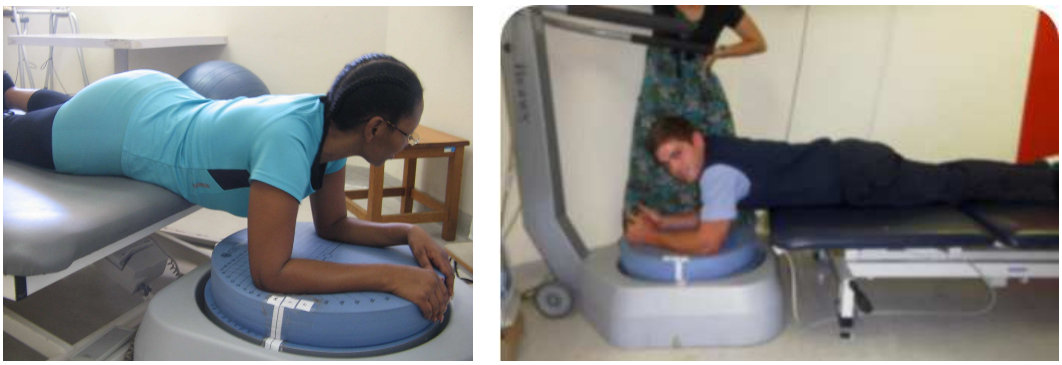
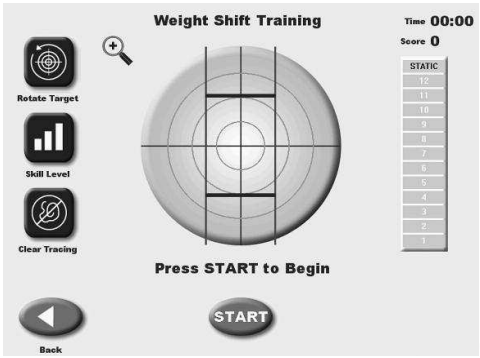


Figure 3.3: Positioning on the BBS

Two different interactive game-like training modes were used on the BBS during the treatment, namely weight-shift training and % weight-shift training.

- *Weight-shift training*: The participant was expected to move/shift weight in the medial–lateral, anterior–posterior and diagonal planes. In this way weight displacement could be achieved in the different planes of movement, as seen in Figure 3.4 (a) and (b).

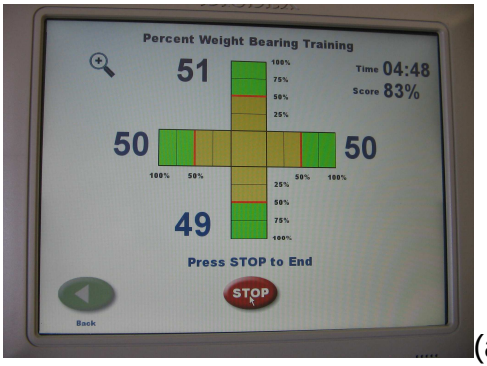


(a)


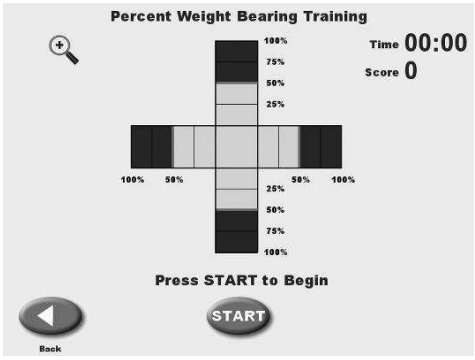
(b)

Figure 3.4: Computerised display of weight shift training
(a) completed training and (b) sample of standardised screen
(Copied from Biodex Medical Systems, Inc., 2011)

- *% Weight-shift training*: The participant was expected to maintain weight in the medial–lateral, anterior–posterior and diagonal planes, as seen in Figure 3.5 (a), (b) and (c). The participant watches the screen; the axis shows green when weight bearing is within target settings. As soon as it turns red, the participant has to move/shift the weight to maintain the 50/50 weight-bearing target. The score is calculated by the percentage time spent within the target range.



(a)



(b)



(c)

Figure 3.5: Computerised display of % weight shift training
(a) patient completed training, (b) sample of training screen and
(c) sample of training screen of medial lateral only
(Copied from Biodex Medical Systems, Inc., 2011)

The researcher documented all the variables in the treatment logbook (Appendix K) for each patient for all treatments.

Treatment 1:

- Treatment 1 started with a stable platform (on level 12). The participant moved the platform as indicated for the set programme. This was done for five minutes or, as quality of movement decreased, the researcher allowed the participant to rest for one to two minutes. After the rest period the same exercise was repeated. The weight-shift training was done only for the first treatment and was repeated twice or for a total of 10 minutes. The researcher monitored the quality of movement continuously. The researcher facilitated the movement and prevented any abnormal movements or any movements that could injure the participant. The screen was used as visual feedback and the researcher gave verbal ques to guide and/or motivate the participant to

execute the best movement/ weight bearing within their potential. All participants included in the study were acute stroke patients in the acute stage the patients present with hypotonicity. Hyper- or hypotonicity was managed by means of facilitation and did not play a role during the execution of the movement. Only one participant presented with fluctuating tone - the tone increased while getting into the position. The participant was positioned in prone and given time to rest; thereafter the tone decreased and the participant was able to perform the training. Participants' trunks were supported on the plinth: participants were excluded if they were unable to keep their heads in the testing and treatment position for at least 10 minutes. During the intervention a rest period was provided as soon as the participants were not able to maintain the upper trunk and head in the required position and it influenced the quality of the movement.

The following occurred during treatments 2 and 3:

Treatment 2 – 3:

- The researcher did not adjust the platform. It was maintained on the stable setting because the participants were unable to tolerate it for longer than five minutes without resting during the previous treatment.
- The treatment entailed of the weight-shift training and the % weight-shift training. Each programme was repeated twice (in accordance with the participant's tolerance). The researcher monitored the quality of movement continuously.
- Rest periods were also limited as the participant progressed.

Treatment 4 – 9:

- The researcher did not adjust the platform. It was maintained on the stable setting because the participants were unable to tolerate it for longer than five minutes without resting.
- Each of the two programmes was repeated four times. The researcher monitored the quality of movement continuously.
- Rest periods also were limited as the participant progressed.

The study participants were re-assessed at one, three and six months post-baseline. The one-month re-assessment consisted of all the outcomes measures included in the pre-testing (see Section 3.6).

At three and six months the re-assessment consisted of a telephonic follow-up interview during which only the WBFPRS and the SF-36v2 Health Survey were assessed. The research assistant conducted the telephonic follow-up assessments (Atif et al., 2013; Maglintea et al., 2012).

All data were captured electronically and checked by a third party for possible errors made during the capturing.

3.6 Outcomes measures

Chapter 2 focused on the composition, validity, reliability and the literature related to the outcomes measures in this study. The next section focuses on the practical application of these outcomes measures during data collection. This information should thus be read in conjunction with the background information provided in Chapter 2.

3.6.1 Fugl-Meyer Assessment Upper Extremity (FMA-UE)

The FMA-UE (Appendix A) was employed to measure functionality in the upper limb. Apparatus utilised with the FMA-UE included a wheelchair, table, reflex hammer, cotton wool, pen/pencil, small piece of cardboard or paper, small can, tennis ball, stop watch and blindfold (see Figure 3.6).



Figure 3.6: Apparatus used for the execution of the FMA-UE

The assessment was performed in a quiet area to ensure maximal concentration and it took about 30 minutes to complete. Clear and concise instructions were given. The participants had to perform the movement with the unaffected limb first. It was demonstrated, and thereafter the participant was asked to repeat the movement on the affected side to obtain the best possible results. The test for coordination/speed was performed only once. The research assistant provided only verbal encouragement. The wrist and hand function was tested independently of the arm (see Section 2.7.1).

3.6.2 Wong-Baker FACES Pain Rating Scale (WBFPRS)

Pain in the shoulder girdle and upper extremity was measured by the WBFPRS (see Appendix B). A laminated representation of the WBFPRS was displayed to the participants to indicate their pain levels after which their responses were documented (see Section 2.7.2). The English and Afrikaans versions of the WBFPRS were used.

3.6.3 Biodex Balance System (BBS)

Shoulder girdle stability was measured using the BBS (see Appendix C). The SI represents the displacement from the level platform position, which can be done unilaterally or bilaterally (Pereira et al., 2008; Cachupe et al., 2001). This dynamic test measures the “patient’s ability to control the platform angle (variance from the locked level/position) and degrees of deflection over time” (Pereira et al., 2008: pg. 669). The greater the variance, the poorer the neuromuscular response thus, a low

score is an indication of better stability and a high score of poor stability (Pereira et al., 2008; Cachupe et al., 2001).

Feedback from the BBS is provided on a monitor and the data/results can be printed after testing. Electronic data/results can be saved and downloaded at a later stage (see Section 2.7.3). Because of the change from the normal positioning, an additional monitor was added for the participants to be able to see their data/results.
For purposes of the study, the postural stability test was used to measure shoulder stability and the test was performed on three levels of stability: 12 (maximum stability = static), 6 (moderate stability) and 1 (no stability).

- Postural Stability Test (PST)

  The PST focuses on patients' ability to maintain their centre of balance and assesses deviations from the centre. A lower score is more desirable than a higher score. The scores consist of an overall SI, Anterior/Posterior Index, Medial/Lateral Index, % time in zone and % time in quadrant (see Figure 3.7).

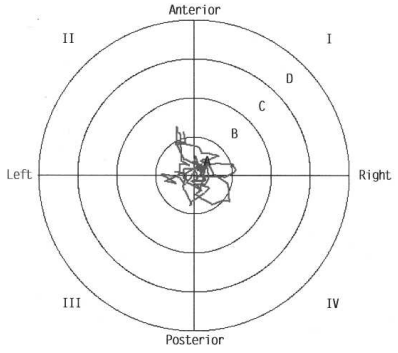


Figure 3.7: Example of PST testing screen
(Copied from Biodex Medical Systems, Inc., 2011).

3.6.4 The SF-36v2 Health Survey

The HRQoL was measured using the SF-36v2 Health Survey (see Appendix D). The SF-36v2 Health Survey is a 36-item stroke-specific scale that assesses the patient's general health status (both physical and QoL) (see Section 2.7.4). It is a multidimensional measure of health status that assesses eight domains of health and provides two physical and mental component summary measures. It takes between five and ten minutes to complete the survey. Patients are asked to indicate their

health state from the alternatives provided on the following eight health domains: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. Each domain scores between 0 and 100. A lower score indicates a weak experience of health status; thus, the higher the score, the better the experience of health status.

3.7 Methodological errors

Table 3.1 gives an outline of methodological errors that could have occurred during the measurement process, as well as the appropriate actions that were taken to limit or prevent these errors.

Table 3.1: Measurement and possible methodological errors

Errors	**Action taken to prevent error**
• Researcher and research assistant were unfamiliar with the procedure and the measurement tools.	• By performing the pilot study the researcher and research assistant familiarised themselves with the necessary procedures of data collection related to the outcomes measures.
• Time limitations and restrictions were anticipated due to availability of the study participants, researcher and research assistant. • Time limitations for performing clinical intervention were anticipated due to the full rehabilitation programme at the Life Rehabilitation Unit (Pasteur Hospital).	• Time schedules were drawn up and distributed to all relevant parties, i.e. the researcher, research assistant, study participants and therapy staff of Life Rehabilitation Unit (Pasteur Hospital).

• Sample size.	• The researcher consulted with the rehabilitation admission consultant on a daily basis to confirm the daily admissions and the planned admissions and discharges for the following week. • All stroke patients admitted were screened for possible participation.
• Drop out/No follow-up.	• Before discharge appointments were scheduled with the participants for the first follow-up. • Phone numbers where verified with the participants, the participants family as well as the social worker. At least two different numbers were documented for each participant. • Each participant was phoned three times on different times during the day. • Appointments were scheduled for the most convenient time to compile the follow-up assessment.
• Valid and reliable outcome measures.	Research on the BBS for the upper limb is a novice field. This study aimed to determine whether the BBS could be used as a valid and reliable outcome measure. The BBS is used to assess and/or treat stability around other joints and also specific for muscle training. The BBS is specifically used for balance and postural stability assessment and training (Pickerill & Harter, 2011; Kovaleski et al. 2009).

• Errors could occur during the finalisation and capturing of data. • Errors could occur during the analysis and interpretation of data.	• Data were checked before analysis. Data also were cross-checked after capturing. • Data analysis was done by the researcher and where appropriate assistance was sought from the Department of Biostatistics of the University of the Witwatersrand.

3.8 Data analysis

a) Hypothesis

The null hypothesis for the study was that upper limb weight-bearing training (using the BBS) would have no effect on the HRQoL, upper-limb function, pain and shoulder girdle stability in patients with hemiplegia post-stroke.

b) Study variables

In this study the dependent variables were:

- shoulder pain as measured by the WBFPRS,
- upper-limb function as measured by the FMA-UE,
- shoulder girdle stability as measured by the PST on the BBS, and
- HRQoL as measured by the SF-36v2 Health Survey.

The independent variables for this study were:

- the treatment intervention on the BBS, and
- personal information of the participants such as age, gender, previous and additional medical history and previous levels of activity.

Data analysis was done using STATA with statistical significance set at $p < 0.05$ (two-sided). Due to the small study population the distribution of the data was not normally distributed for the intervention part of the study and non-parametric tests were used for the data analysis.

All demographic information was summarised using descriptive statistics (frequencies, means and standard deviations) and will be displayed in tables and graphs.

For baseline comparison between the two groups, which were independent samples, the Mann-Whitney test (non-parametric test) was performed to compare the independent observations for shoulder girdle stability, upper-limb function and HRQoL as outlined in the objectives.

For baseline comparison between the two groups as well as for the pre- and post-intervention, the Fisher's exact was performed for pain.

For the pre- and post-intervention comparison in each group, the Mann-Whitney test (non-parametric test) was performed to compare the independent observations for shoulder girdle stability, upper-limb function and HRQoL.

A univariate analysis was done for all four time periods (baseline, one month, three months and six months post-baseline). For binary data the logistic regression analysis was used and for interval/ratio data the wald chi 2 regression analysis was done. The regression analysis was done for the HRQoL although it was a small sample as it has been indicated that the bigger the input of data (this study had four different timeframes) the higher the power of the data.

To establish the differences in response to the intervention at the various time points of measurement, the Mixed Effect Model was used. To establish the factors that influenced shoulder girdle stability, a bivariate analysis was done (without a multiple regression analysis) because of the small sample size. The two sample Wilcoxon

rank sum (Mann-Whitney) test was used to assist with selecting factors that influenced shoulder girdle stability.

An “intention-to-treat analysis” was used: all data collected from all the included participants were analysed, even though there might have been missing data (Sapoka et al., 2010).

3.9 Conclusion

This chapter explained in detail the research methodology applied in this study. The next chapter consists of a description of the demographic information of the participants and the results of the tests performed.

CHAPTER 4

4. RESULTS OF THE STUDY

4.1 Introduction

In this chapter the most important results of the study are summarised using tables and paragraphs amongst others. The inclusion procedure and reasons for exclusion are explained. Loss to follow-up that occurred during the study is explained and the reasons for the drop-out of participants are outlined.

Discussions are provided of the results on shoulder girdle stability and upper limb function in hemiplegia post-stroke participants over a period of one month, using the BBS. In addition, the results on the effect of shoulder stability training using the BBS on pain and HRQoL over a period of six months are described. Factors associated with shoulder girdle stability are identified. The implications of the results are discussed in more detail in Chapter 5. Owing to the small study population the data were not normally distributed.

4.2 Inclusion

A total of 145 post-stroke patients were screened at the Life Rehabilitation Unit (Pasteur Hospital) for possible inclusion in the study. The mean age of the participants was 61 (±15) years and there were no differences in the distribution of age between genders.

Additional demographic information of patients screened is shown in Table 4.1.

Table 4.1: Demographic information of patients screened (n = 145)

Characteristics		**n (%)**
Gender	Male	67 (46.2)
	Female	78 (53.8)
Side of body affected	Left-sided hemiplegia	68 (46.9)
	Right-sided hemiplegia	65 (44.8)
	Bilateral hemiplegia	12 (8.3)

Of these patients, 128 (88.28%) were excluded due to reasons as summarised in Table 4.2.

Table 4.2: Reasons for exclusion (n = 128)

Reason			**n (%)**
Impaired vision			7 (4.8)
Poor FIM/FAM score on admission			83 (57.2)
Impaired cognition based on the mini-mental screening			75 (51.7)
Aphasia	Global	31 (40.3)	77 (53.1)
	Expressive	32 (41.6)	
	Receptive	14 (18.2)	
Declined participation			5 (3.5)
Medically unstable			18 (12.4)
Extreme shoulder instability and/or pain			2 (1.4)

In several cases patients met multiple exclusion criteria as presented in Table 4.2.

4.3 Loss to follow-up

A total of 17 participants were enrolled at baseline. At baseline and one-month follow-up post-baseline physical outcomes measures for shoulder girdle stability and upper limb function were performed, and the WBFPRS and the SF-36v2 was administered for pain and HRQoL (n = 17). The baseline and one-month follow-up post-baseline were performed while the participants were admitted to the Life Rehabilitation Unit (Pasteur Hospital).

No physical outcomes measures could be performed at the three- and six-months follow-up post-baseline because only one participant resided in Bloemfontein and the majority (94%) of the participants were unable to return to Bloemfontein for testing.
At the three- and six-months' follow-up post-baseline only the WBFPRS and the SF-36v2 were administered for pain and HRQoL and were performed telephonically (n = 9). Eight participants were lost to follow-up from three months onwards. The following diagram (Figure 4.1) depicts the loss to follow-up over the duration of the study.

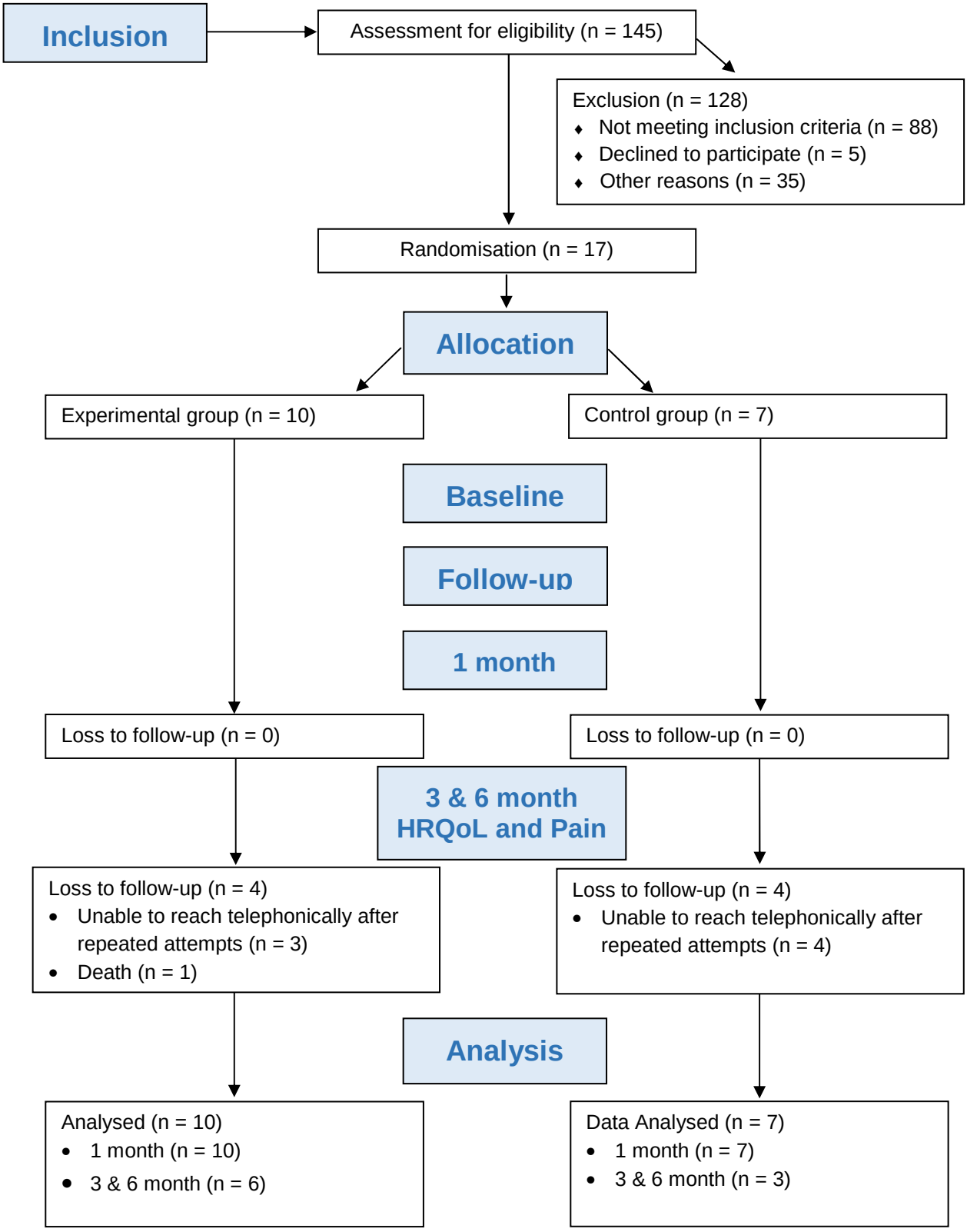


Figure 4.1: Flow of study participants

4.4 Demographic information of the study participants

A total of 17 participants were included in the main study after screening. Of the 17 study participants ten were allocated to the experimental group and seven were allocated to the control group. The demographic details and the clinical characteristics of the study participants are shown in Table 4.3 below. The median length of stay (LOS) for the participants was 32 days. The age of the participants ranged between 32 and 80 years, with a median age of 53 (11.79) years.

The control group comprised five female and two male participants, while the experimental group comprised three female and seven male participants. The control group contained two participants with left-sided hemiplegia and five with right-sided, whereas the experimental group contained seven with left-sided hemiplegia and three right-sided. All the participants in the control group were right-handed, implying that more of them had their dominant hand affected than those in the experimental group.

The age of the participants in the control group ranged from 32 to 80 years with a median age of 48 (16.51) years, while the age of the experimental group ranged from 45 to 69 years with a median age of 54 (8.08) years.

The demographic information of the study participants is shown in Table 4.3.

Table 4.3: Demographic details of the study sample (n = 17)

Characteristics		n (%)	Control	Experi-mental
Total sample		17 (100)	7	10
Gender	Male	9 (53)	2	7
	Female	8 (47)	5	3
Median age in years (SD)	Overall	53 (±11.8)	53 (16.5)	55 (8.5)
	Male	49 (13.2)	60.6 (27.5)	53 (13.56)
	Female	54 (10.5)	49 (9.8)	55 (2.1)
Side of body affected	Left-sided hemiplegia	9 (52.9)	2	7
	Right-sided hemiplegia	8 (47.1)	5	3
Stroke subtype	Haemorrhage	1 (5.9)	1	0
	Infarct	9 (52.9)	4	5
	Not specified	7 (41.2)	2	5
Employment status at admission	Employed	15 (88.2)	6	9
	Unemployed	1 (5.9)	0	1
	Pensioner	1 (5.9)	1	0
Identifiable risk factors of stroke	Hypertension	12 (70.6)	4	8
	Diabetes	7 (41.2)	2	5
	Cholesterol	5 (29.4)	1	4
	Heart disease	2 (11.8)	0	2
	Hormone therapy	1 (5.9)	0	1
	Smoking	1 (5.9)	0	1
	Alcohol abuse	1 (5.9)	0	1

** For the purpose of this study a pensioner was a person older than 60 years who was retired.*
** Values are frequencies and percentages unless otherwise indicated.*

The number of left-sided hemiplegics was similar to the number of right-sided hemiplegics included in the study. All the participants were right-handed implying, that 47.1% had their dominant hand affected. Some participants presented with multiple risk factors for stroke (Table 4.3), with hypertension (70.6%) being the most frequently noted risk factor, followed by diabetes (41.2%).

Table 4.4: Baseline comparison for all the outcome measures (n=17)

	Control group (n = 7)	Experimental group (n = 10)	p-value
Shoulder girdle stability			
Level 12 Mean (SD)	2.46 (1.58)	2.51 (2.95)	0.69
Level 6 Mean (SD)	0.86 (0.37)	0.67 (0.68)	0.06
Level 1 Mean (SD)	1.09 (0.79)	0.82 (0.83)	0.38
Upper limb function			
A. Upper extremity	11.14 (10.06)	20.2 (10.84)	0.07
B. Wrist	2.29 (3.95)	4.60 (4.30)	0.24
C. Hand	3.14 (4.88)	5.80 (5.85)	0.35
D. Coordination	1.00 (1.53)	2.10 (2.23)	0.33
H. Sensation	10.57 (2.23)	9.70 (2.75)	0.43
J. Passive joint motion	20.57 (2.30)	22.1 (2.08)	0.12
Total	72.00 (19.44)	73.75 (40.34)	0.50
Upper limb pain			
0	4 (57.1)	10 (100)	0.05
2	1 (14.3)	0 (0)	
4	2 (28.6)	0 (0)	
HRQoL			
Physical function Mean (SD)	2.86 (4.88)	6.5 (9.14)	0.41
Role limitation due to physical health Mean (SD)	6.25 (10.83)	5.63 (10.40)	0.95
Role limitation due to emotional problems Mean (SD)	50 (38.19)	85 (33.75)	0.03
Energy/ fatigue Mean (SD)	53.57 (16.08)	65.63 (31.63)	0.25
Emotional well-being Mean (SD)	66.43 (21.93)	75.5 (29.48)	0.42
Social functioning Mean (SD)	42.86 (34.50)	27.5 (24.15)	0.32
Pain Mean (SD)	75 (25)	97.5 (5.27)	0.05
General health Mean (SD)	73.57 (11.80)	67.5 (23.72)	0.96
Health change Mean (SD)	14.29 (13.36)	25 (28.87)	0.47

At baseline the two groups were comparable considering shoulder girdle stability, upper-limb function and the HRQoL (see Table 4.4). But at baseline the two groups were not comparable with regard to pain as the control group experienced significantly more pain than experimental group (see Table 4.4).

4.5 The effect of shoulder girdle stability training on shoulder girdle stability

Shoulder girdle stability was determined using the BBS at baseline and at one month follow-up post-baseline for three levels of stability (Level 12 – static, Level 6 – unstable, Level 1 – most unstable). The computed score for shoulder girdle stability is reflected in Table 4.5.

Table 4.5: Shoulder girdle stability at baseline and one month follow-up (n = 17)

Time period	**Baseline**			**1 month**		
Group	Control group (n = 7)	Experimental group (n = 10)	p-value	Control group (n = 7)	Experimental group (n = 10)	p-value
Level 12 Mean (SD)	2.46 (1.58)	2.51 (2.95)	0.69	0.83 (0.51)	3.39 (6.09)	0.77
Level 6 Mean (SD)	0.86 (0.37)	0.67 (0.68)	0.06	0.58 (0.46)	0.68 (0.72)	0.96
Level 1 Mean (SD)	1.09 (0.79)	0.82 (0.83)	0.38	0.44 (0.29)	1.22 (1.81)	0.24

** A value closer to 0.0 indicates a better value for shoulder girdle stability.*
** Shoulder girdle stability was not measured at 3 and 6 months.*

No statistically significant difference was found in shoulder girdle stability between the control and experimental groups at neither baseline nor one-month follow-up post-baseline for any of the three levels tested.

4.6 The effect of shoulder girdle stability training on upper limb function

Upper-limb function was measured at baseline and one-month follow-up post-baseline using the FMA-UE. The FMA-UE comprises six domains, which are tallied to provide a total score for upper-limb function. The following (Table 4.6) is a summary of baseline and one-month follow-up post-baseline for upper-limb function (FMA-UE).

Table 4.6: Between-group comparison of upper limb function during the study period (n = 17)

Time period	Upper limb domain	Control group Mean score (SD)	Experimental group Mean score (SD)	p-value
Baseline (n = 17)	A. Upper extremity	11.14 (10.06)	20.2 (10.84)	0.07
	B. Wrist	2.29 (3.95)	4.60 (4.30)	0.24
	C. Hand	3.14 (4.88)	5.80 (5.85)	0.35
	D. Coordination	1.00 (1.53)	2.10 (2.23)	0.33
	H. Sensation	10.57 (2.23)	9.70 (2.75)	0.43
	J. Passive joint motion	20.57 (2.30)	22.1 (2.08)	0.12
	Total	72.00 (19.44)	73.75 (40.34)	0.50
1 month (n = 17)	A. Upper extremity	18 (12.71)	22.3 (10.61)	0.49
	B. Wrist	4.14 (4.49)	6.40 (4.53)	0.36
	C. Hand	5.14 (6.23)	7.60 (6.20)	0.58
	D. Coordination	1.86 (2.48)	2.30 (2.16)	0.58
	H. Sensation	11.71 (0.76)	10.80 (1.93)	0.25
	J. Passive joint motion	23.00 (1.53)	22.80 (2.80)	0.82
	Total	87.857 (25.41)	80.166 (43.13)	0.93

** A total score of 0–35 = very severe impairment, 36–55 = severe impairment, 56–79 = moderate impairment and > 79 = mild impairment.*

** Upper limb function was not measured at 3 and 6 months.*

There was no difference between the mean total score for upper-limb function of both the control and the experimental groups at baseline, with both groups having moderately impaired upper-limb function. Similarly, there was no difference at one month follow-up post-baseline between the mean total score for both groups. It was notable that the severity of upper-limb function improved to mild impairment in both groups.

4.7 The effect of shoulder girdle stability training on upper limb pain

Upper-limb pain was measured at baseline, one month, three months and six months follow-up post-baseline using the WBFPRS. The presence and severity of pain experienced by the participants are summarised in Table 4.7.

Table 4.7: Between group comparisons of upper-limb pain over the study period (n=17)

Time period	Group	Severity						p-value
		0	2	4	6	8	10	
Baseline	Control (n=7) n (%)	4 (57.1)	1 (14.3)	2 (28.6)	0 (0)	0 (0)	0 (0)	0.05
	Experimental (n=10) n (%)	10 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
1 month	Control (n=7) n (%)	3 (42.9)	0 (0)	2 (28.6)	1 (14.3)	1 (14.3)	0 (0)	0.02
	Experimental (n=10) n (%)	10 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
3 months	Control (n=3) n (%)	1 (33.3)	0 (0)	0 (0)	2 (66.7)	0 (0)	0 (0)	0.17
	Experimental (n=6) n (%)	5 (83.3)	0 (0)	0 (0)	0 (0)	1 (16.7)	0 (0)	
6 months	Control (n=3) n (%)	1 (33.3)	0 (0)	1 (33.3)	1 (33.3)	0 (0)	0 (0)	0.12
	Experimental (n=6) n (%)	6 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	

** Where 0 = No hurt, 2 = Hurts little bit, 4 = Hurts little more, 6 = Hurts even more, 8 = Hurts whole lot and 10 = Hurts worst.*

** Eight participants were lost to follow-up from three months onwards.*

At baseline and three-months' follow-up post-baseline, statistically significant differences were found in the pain experienced between the two groups. No participants in the experimental group experienced any pain at baseline. However, no statistically significant differences between the two groups were found at three and six months.

4.8 The effect of shoulder girdle stability training on HRQoL

HRQoL was measured using the SF-36v2 and was measured at baseline, one month, three months and six months' follow-up post-baseline. The SF-36v2 reports on nine domains relating to physical functioning aspects regarding HRQoL. Table 4.8 shows the mean HRQoL scores as measured for the two groups over the duration of the study.

Table 4.8: The mean HRQoL scores as measured by the SF-36v2 over the duration of the study (n = 17)

Time period	Group	Physical function Mean (SD)	Role limitation due to physical health Mean (SD)	Role limitation due to emotional problems Mean (SD)	Energy/ fatigue Mean (SD)	Emotional well-being Mean (SD)	Social functioning Mean (SD)	Pain Mean (SD)	General health Mean (SD)	Health change Mean (SD)
Base-line	Control	2.86 (4.88)	6.25 (10.83)	50 (38.19)	53.57 (16.08)	66.43 (21.93)	42.86 (34.50)	75 (25)	73.57 (11.80)	14.29 (13.36)
	Experimental	6.5 (9.14)	5.63 (10.40)	85 (33.75)	65.63 (31.63)	75.5 (29.48)	27.5 (24.15)	97.5 (5.27)	67.5 (23.72)	25 (28.87)
	p-value	0.41	0.95	**0.03**	0.25	0.42	0.32	**0.05**	0.96	0.47
1 month	Control	25 (35.36)	23.21 (38.48)	83.33 (34.37)	66.07 (25.22)	76.428	60.71 (32.62)	82.14 (24.85)	80 (15.275	25 (20.41)
	Experimental	28 (31.99)	22.5 (22.86)	80 (34.96)	68.13 (24.55)	81 (17.13)	31.25 (25.85)	97.5 (5.27)	77 (19.18)	25 (23.57)
	p-value	1.00	0.64	0.86	0.81	0.59	**0.05**	0.18	0.77	0.88
3 month	Control	50 (47.70)	62.5 (33.07)	100 (0)	75 (21.65)	86.67 (23.09)	79.17 (19.09)	75 (21.65)	86.67 (7.64)	50 (43.30)
	Experimental	40 (34.06)	58.33 (25.82)	91.67 (20.41)	65.63 (9.48)	93.33 (6.06)	75 (38.73)	89.58 (20.03)	87.5 (4.18)	37.5 (20.92)
	p-value	0.80	0.79	0.48	0.79	0.79	0.68	0.39	0.67	0.58
6 month	Control	48.33 (50.08)	58.33 (52.04)	100 (0)	93.75 (6.25)	96.67 (5.77)	100 (0)	83.33 (14.43)	83.33 (5.77)	50 (43.30)
	Experimental	50 (40.62)	76.04 (22.50)	91.67 (20.41)	82.29 (17.86)	94.17 (8.01)	85.42 (22.94)	100 (0)	86.11 (6.97)	41.67 (20.41)
	p-value	0.90	0.69	0.48	0.51	0.67	0.29	**0.03**	0.36	0.59

** Eight participants were lost to follow-up from three months onwards.*
** Each domain scores between 0 and 100. The lower the score, the greater the disability; the higher the score, the less the disability.*

At baseline a statistically significant difference was found regarding the impact of emotional problems on role limitation (p = 0.03), and pain (p = 0.05) between the two groups, where the experimental group indicated better values. At one month a statistically significant difference was found regarding the extent of impaired social function (p = 0.05) between the two groups and the control group indicated better values.

No statistically significant differences were noted at three-months follow-up post-baseline between the two groups. At six months a statistically significant difference was found regarding pain between the two groups (p = 0.03), the experimental group indicated better values.

Regressional analysis was performed in order to determine the reported change in health on the SF-36v2 and the shoulder girdle stability from baseline over the six-months follow-up period (see Table 4.9).

Table 4.9: Reported change in health from baseline over the duration of the study for the experimental group

Health change	**OR.**	**Std.**	**z-value**	**p-value**	**95% CI**
Experimental group	1.54	0.99	0.67	0.50	0.43–5.47
1 month (n = 10)	1.00				
3 months (n = 6)	10.87	8.97	2.89	0.004	2.15–54.80
6 months (n = 6)	9.25	7.73	2.66	0.008	1.79–47.62

The participants in the experimental group reported significantly improved health from baseline at both three- and six months follow-up post-baseline. The participants in the experimental group, therefore, were more likely to have experienced improved health over time post-stroke.

4.9 Factors associated with shoulder girdle stability

A univariate analysis was performed in order to identify factors that may influence shoulder girdle stability, as reported in Table 4.10.

Table 4.10: Factors associated with shoulder girdle stability (n = 17)

Factor	z-value	p-value
Gender	–1.83	0.07
Alcohol abuse	1.63	0.10
Hormone therapy	–1.43	0.15
Side affected	1.35	0.18
Cholesterol	1.16	0.25
Age	0.20	0.44
Length of stay	0.18	0.49
Smoking	–0.41	0.68
Diabetes	0.29	0.77
Hypertension	0.21	0.83
Heart disease	0.00	1.00

Based on the findings of this study, none of these factors investigated were likely to have influenced shoulder girdle stability.

4.8 Conclusion regarding results

The gender distribution between the experimental and control group was skewed, with more females in the control group and more males in the experimental group (see Table 4.3). This is attributed to the small sample size and the random assignment of participants to the groups.

The study found no statistically significant difference in shoulder girdle stability between the control and experimental groups at one-month follow-up post-baseline for any of the three levels tested as determined on the BBS.

The severity of the impairment of upper-limb function for both the control and the experimental group was similar at baseline and improved from moderate to mild over the duration of the study.

At baseline the control group experienced significantly more pain measured with the WBFPRS compared to the experimental group, despite shoulder girdle stability and the severity of upper limb function being similar. This corresponded with the findings on the SF-36v2 for pain at baseline and six months, indicating that the control group experienced more pain.

The participants in the experimental group reported significantly improved health over time. The implications of these findings will be discussed in more detail in Chapter 5.

CHAPTER 5

5. DISCUSSION THE STUDY FINDINGS

5.1 Introduction

In this chapter is devoted to an in-depth discussion of the findings of the study in the context of available literature, and possible reasons for the findings are provided. Inclusion in and loss to follow-up played an important role in the outcome of the study and, thus, are discussed as well. In addition, the impact of shoulder girdle stability training in hemiplegic post-stroke participants using the BBS on shoulder girdle stability, upper-limb function, pain and HRQoL are discussed, while factors associated with shoulder girdle stability are addressed.

5.2 Inclusion in and loss to follow-up

A total of 17 (11.74%) participants were included in the main study after screening. In several cases patients were excluded because they met multiple exclusion criteria (see Section 3.4.2 and Table 4.1). These criteria are associated with risk factors and factors that have an impact on stroke as discussed (see Sections 2.2 and 2.5).

The researcher was unable to repeat the measures for shoulder stability and upper-limb function at the three- and six-months follow-up post-baseline (see Sections 3.4 and 4.3) due to participants' not having the financial means to travel to Bloemfontein for study follow-up. About 94% of the participants did not reside in Bloemfontein and most of the participants were also dependent on transport provided by other individuals. Unfortunately, the researcher had no funding available for transport fees for participants. This, therefore, necessitated the telephonic follow-up at three and six months.

For the telephonic follow-up 47.05% of the participants were lost to follow-up (see Figure 4.1) due to various reasons as indicated in Chapter 4 (Section 4.3). Various

reasons exist for loss to follow-up: participants might have passed away, their health might have improved or deteriorated health, it may also be due to practical reasons (change of names, addresses and phone numbers), or personal circumstances, or participants simply might be noncompliant and/or have lost interest (Kaur et al., 2014). In this study only one participant sadly passed away. As for the remainder the research assistant after multiple attempts was unable to reach other participants telephonically; times scheduled by the research assistant did not suit some participants; and some participants might not have had a clear understanding of the importance and the value of the research.

Loss to follow up decreases the validity of the study (Kaur et al., 2014; Akl et al., 2012, Liu et al., 2006). Previous research demonstrated that loss to follow-up are higher with rehabilitation or physiotherapy Kaur et al., 2014) and were higher in the intervention group than the control group (Akl et al., 2012). In a study reported by Douiri et al. (2013) it was indicated that healthier participants and those from higher socio-economic groups might be more likely to engage in research follow-up. The best strategy to limit loss to follow-up is prevention (Akl et al., 2012, Armijo-Olivo et al., 2009; Liu et al., 2006). Table 5.1 provides suggestions from another study (Kaur et al., 2014) to limit loss to follow-up and what the researcher have did to address these.

The impact that the high loss to follow-up had on this study was an even smaller study sample to be analysed at three and six month s' follow-up which impacted the low statistical power.

Table 5.1: Suggestions to limit loss to follow-up and what the researcher did.

Kaur et al., 2014	This study
Complete questionnaires via telephone or send them in the mail.	Telephonic follow-up was done at three and six months to ensure that the questions were asked in the exact same manner as during the baseline and one-month post-baseline assessment.
Involve the patient's family/caregivers.	Telephone numbers of the family members also were documented and they were contacted in cases of no response from the participants.
Conduct the follow-up visits at a location convenient for the patient if possible and arrange transportation to the visit location or reimburse the transportation costs.	Participants did not reside in Bloemfontein and most of the participants were dependent on transport provided by other individuals; telephonic follow-up was done.
Provide opportunity for building social support by means of organized group educational sessions.	Participants were motivated to continue with therapy or referred if the researcher became aware of other problems.
Keep in touch, schedule appointments in advance and send reminders. Make it convenient for the participant. Keep follow-up short and collect only what is absolutely necessary to answer the research question. Allow rest between interviews/tests as needed.	Appointments, dates and times were scheduled with the participants. Only the necessary information was required from the participants.
Employ well-trained research personnel and allow time to bond.	The research assistant completed all the assessments and was familiar with the measurement tool as well as the participants.

5.3 Demographic details of the study participants

The study sample consisted of nine (53%) males and eight (47%) females (see Table 4.3). Appelros et al. (2009) contend that stroke is 33% more common among males than females worldwide, but Foerch et al. (2013) indicated a variance in the gender distribution of acute stroke patients in different countries. Some of the reasons mentioned were prevalence of medical risk factors such as hypertension, diabetes mellitus, heart diseases and atrial fibrillation, as well as age differences and smoking (Foerch et al., 2013). The ages of participants in this study ranged between 32 and 80 years with a mean age of 54 years. The mean age of the eight females was 52 years and that of the males 55 years. According to the literature, the mean age of patients (see Section 2.2) experiencing stroke is between the ages of 70 and 79 years, with 70 years being the mean age in males and 75 years in females (De Weerd et al., 2012; Mohammad et al., 2012). The youngest participant was a female and the oldest participant was a male - both these participants were in the control group. Therefore, it is clear that the participants in this study were younger than those in comparable studies conducted in developed countries and reported in literature. Studies performed previously in South Africa on stroke patients substantiate these findings of the present study (Maredza et al., 2015; Parekh & Rhoda, 2013; Mudzi et al., 2012). Possible reasons for this may the increase of infectious diseases, including HIV/AIDS (Afridi et al., 2015; Worm et al., 2010), and even the use of anti-retroviral medication (Worm et al., 2010). Diseases related to poverty, malnutrition and urbanisation also cause an increase in the risk factors for vascular disease, and so do excessive alcohol use, physical inactivity, unhealthy diets, obesity and smoking (Connor et al., 2005; Van der Sande et al., 2001; Walker et al., 2000).

The three most identifiable risk factors (see Section 2.2 and Table 4.3) that this study's participants presented with were hypertension (70.59%), diabetes (41.18%) and high cholesterol (29.41%). These findings are supported by the findings of a study by Connor et al. (2005), in which 70% of the participants presented with one or more risk factors and 40% with two or more risk factors. In the current study some of the participants also presented with more than one risk factor. The experimental group presented with more risk factors than the control group. Hypertension has

been identified worldwide as the risk factor with the highest incidence (55.6%), followed by ischemic heart disease (30.7%), diabetes (18.6%) and high cholesterol (15%) (De Jesús Llibre et al., 2010; Sridharan et al., 2009). Diabetes has been identified as the most common risk factor in the Asian population (24%) (Connor et al., 2005). The results of the current study agree with those found in other South African studies which identified the most prevalent risk factors as hypertension (95%), cigarette smoking (76%), obesity (36%), current alcohol use (20%) and diabetes mellitus (12%) (Rouillard et al., 2012; Thorogood et al., 2007; SASPI Project Team, 2004; Rhoda & Hendry, 2003). In the study reported here, only 11.8% of the participants presented with heart disease and 5.9% of the participants indicated that they are smoked and used of excessive alcohol - all these participants were in the experimental group. Therefore, it is clear from the data that the risk factors of the participants in the Bloemfontein study did not differ from the risk factors identified in other studies in South Africa and worldwide. The implications of these findings indicate that the age of stroke patients is decreasing (getting younger) and there is a more or less equal distribution between male and female. Similar identifiable risk factors were observed, and most of the participants did not merely present with a single risk factor.

The final number of participants was assigned randomly to either the control group or the experimental group. The researcher made use of a simple random sample where each participant had an equal probability of being chosen, as it was meant to be an unbiased representation of the group (Rajagopalan et al., 2013; Sapoka et al., 2010). No gender stratification was done; therefore, the control group contained more females and the experimental group contained more males. Due to not making use of stratified sampling the groups were skewed and the researcher could not draw conclusions which might have assisted to account for the differences within the groups (such as age and/or gender).

5.4 The effect of shoulder stability training on shoulder girdle stability

No statistically significant difference was found between the two groups' shoulder girdle stability on any of the three stability levels at the one month post-baseline

follow-up (see Section 4.5). Unfortunately, no values could be obtained at three and six months due to loss to follow-up due to patients not being able to return for follow-up measurements and rehabilitation centre logistics which were stipulated before implementation of the study (see Section 6.3).

Although the differences were not statistically significant, the results indicated that the mean values for level 6 (unstable) were closest to 0.0. The results also indicated that it was easier for participants to maintain stability on a platform that allowed some degree of movement instead of on a static or unstable platform. The literature suggests that performing the exercise on an unstable surface leads to greater muscle activity in an attempt to achieve greater stability (Sandhu et al., 2008; Behm et al., 2002). For this reason, better co-contraction of muscles (surrounding the shoulder girdle) might have occurred in participants during increase in movement of the platform (see Sections 2.3, 2.6 and 2.7.3). The activity of the antagonists will also increase on an unstable base of support in an attempt to control the position of the limb (Pattern et al., 2006) to prevent injuries.

This viewpoint (better stability on level 6 on the BBS) is supported by findings from pilot studies conducted by Botha et al. (2014) and Ferreira et al. (2015). These studies sought to establish reference intervals for shoulder girdle stability on the BBS. Botha et al. (2014) conducted their study on an elderly population (65–75 years), whereas Ferreira et al. (2015) conducted their study on a younger population (18–24 years). Their studies also indicated better values at level 6 instability when using the BBS (Ferreira et al., 2015; Botha et al., 2014).

It is difficult to compare findings and draw clear conclusions from the various studies performed (determining the reference intervals for shoulder girdle stability), because the methodology varies significantly with regard to selection criteria, intervention and outcomes measures. It is important to consider assessing unilateral shoulder stability in a more sensitive and reliable manner and reducing compensatory and trick movements. In this study, BBS was used in a novel way by applying it during upper limb stability training to determine shoulder girdle stability. However, the researcher found it difficult to recruit patients who could tolerate the BBS and the measurement

positions needed for the execution of the study. For this reason, the data collection process took longer than anticipated. The suitability of the BBS in shoulder stability training , therefore, is questionable. However, it should be noted that, given a larger sample size, different results might have been found.

Another confounding factor associated with the ability to establish the effect of shoulder girdle stability training on the BBS was that both groups received standard rehabilitation and the BBS was only an add-on intervention strategy for the experimental group. Thus, any change in the outcome of shoulder girdle stability cannot be attributed directly and solely to the BBS. This often might be the case in randomized control trials, where the intervention only forms a small part of the standard rehabilitation and may not indicate additional improvement (Shadish et al., 2008; Prange et al., 2006; Sze et al., 2002). Rehabilitation units are effective in improving short-term survival, functional abilities and increasing independence (Parekh & Rhoda, 2013; Stroke Unit Trialists' Collaboration, 2007).

5.5 The effect of shoulder stability training using the BBS on upper limb function

At baseline all the participants in this study sample showed moderate impairment (see Table 4.6) of their upper-limb function. There was no significant difference in upper limb function between the control and the experimental group after one month. Although the experimental group indicated better mean values, the standard deviation was also larger, which indicated a greater variance between the lowest and highest scores of those participants. This could be ascribed to the small sample size of this study, as well as the random assignment of the groups without stratification (leading to an unequal distribution). Accurate or clear conclusions regarding the effectiveness of the BBS training on the upper-limb function cannot be drawn from these study findings alone due to the lack of differences found between the two groups. It is, therefore, possible that the BBS did not influence the upper-limb muscles and, hence, upper limb function.

However, it is possible that, with a longer follow-up period and in combination with medical follow-up, a positive effect of the BBS on upper-limb function could have been established. This is supported by the slight improvement in the upper-limb function (though not statistically significant) at the one month follow-up post-baseline as shown by the decrease of upper-limb impairment severity from moderate (73.75) to mild (80.166) (refer to Table 4.6). Duncan et al. (2000) report that the most evident recovery of neurological impairments occurs within the acute phase (first month), although neurological recovery still maybe observed in patients for up to six months post-stroke. A possible reason for this may be that, in the early stages post-stroke patients tend to be more dependent for ADL on family or nursing staff but, after discharge, with the realisation that movement and/or function is not returning, they try to become more independent (Rhoda et al., 2011).

Other factors affecting post-stroke outcomes were identified as disability on admission, dysphagia, age, severity of the hemiplegia, continence and ADL performance (Gialanella et al., 2012; Meijer et al., 2003) (see Section 2.6). Hospitalisation, especially the concomitant availability of carers, has an influence on the individual's ability to make decisions and become more independent. After being discharged, the individual might have no choice but to become more independent with regard to ADL. This may result in the increased use of compensatory movement patterns to perform ADL in order to become independent in the home environment and may negatively impact the long-term outcome and functionality. On the other hand, overprotective caregivers also may contribute to further reduction in the patient's ability to function, as they tend to do everything for the patient (Mamabolo et al., 2009).

With regard to the individual components of the FMA-UE the experimental group indicated better movement of the upper extremity, wrist and hand, as well as coordination, but indicated lower mean scores with regard to their sensation and passive joint motion (refer to Table 4.6). Possible reasons for this may be severity of the stroke or the presentation of the patient post-stroke, although the researcher did not aim to assess these factors. Brewer et al. (2012) state that post-stroke loss of sensation is associated with stroke severity and may influence upper-limb function

(see Section 2.4). The absence of selective movement may lead to abnormal movement patterns and therefore prevent the joint moving through the full range of motion (Lang et al., 2012).

Functional recovery post-stroke (see Section 2.6.1) is not only dependent on the rehabilitation process but also is influenced by patient-specific factors including stroke severity, patient motivation and age (Brewer et al., 2012; Barreca et al., 2003). Motor recovery is related to the degree of initial severity and the amount of time before voluntary movements are initiated (Takeuchi & Izumi, 2013). During this study period, all the participants continued with their standard therapy programme of three and a half hours after which the study intervention (BBS shoulder girdle stability training) was performed (see Section 3.4.1). This might have resulted in the participants being fatigued and not using their muscles optimally as required during the activities for the study and measurements. Most of the participants had limited voluntary movements (ranging from no active movement to mere flickers of movement in the muscle on the Oxford grading scale) to initiate optimal movement.

During this study the participants' trunks were supported and stabilised on a plinth during the shoulder stability training. In a study by Kang et al. (2014) the results indicated that the use of trunk restraint resulted in significant gains in active ROM of the upper limb (reduced trunk movement, increased shoulder and elbow movement) and showed similar improvement in the upper-limb function. The opposite effect was noted with the participants who did not receive trunk restraint during movements (Kang et al., 2014). The use of compensatory mechanisms (atypical movements) (see Sections 2.4 and 2.6) may improve motor function in the short term, but could eventually be associated with other complications such as shoulder pain and decreased ROM of the upper-limb joints and trunk (Kang et al., 2014; Lum et al., 2009). The participants in this study were positioned and stabilised (see Section 3.5.2) to prevent any atypical movements and to initiate the co-contraction required around the shoulder girdle.

The generally poor upper-limb functioning of the participants in this study raises concern; although this finding is concordant with what has been found in the context

of literature, indicating that the upper limb has a poor functional outcome (see Sections 2.2 and 2.6). Although the experimental group received BBS training in addition to standard care, no difference was noted regarding the change in upper-limb function – both groups changed from moderate to mild impairment with regard to their upper-limb function at one month. Many explanations can be offered for this finding. Part of it could be due to the shorter duration of hospitalisation stay (for stroke rehabilitation purposes, the median was about four weeks in this study). In South Africa post-stroke patients are discharged from hospital with low functional status – this tendency is even worse in the public sector than in the private sector (Mamabolo et al., 2009). A minimum hospital stay of at least two weeks and a stay of more than six weeks may increase the probability of increased functionality (Rhoda et al., 2015; Mamabolo et al., 2009; Chae et al., 2007). A study by Mudzi et al. (2012) determined that the duration of post-stroke hospital stay at the Chris Hani Baragwanath Hospital (public sector) was found to be an average of six days. It is, however, important to remember that functional independence cannot always be attributed to the duration of hospitalisation, because other factors such as a lack of the availability of early rehabilitation could increase chances of long-term complications and decreased functionality (Rhoda et al., 2015; Mamabolo et al., 2009; Chae et al., 2007). Although the length of hospitalisation in this study was longer than four weeks, it did not translate to more improvement in upper limb function in this cohort.

Good shoulder function (see Section 2.3) is a requirement for effective hand function, as well as for the execution of ADL. This is especially true when considering that 47.1% of the study participants' dominant upper limb and hand were affected. Handgrip strength depends on the coordination between finger and wrist flexors and extensors. The control of distal motor activity post-stroke is dependent on the activation of proximal stabilisation muscles (Kang et al., 2014). The level of upper-limb impairment, prevalent in this study sample, is a cause of concern, because it could be tested only at one month and the control group indicated better shoulder girdle stability (closer to 0.0) values when tested at baseline and one month (see Sections 4.5 and 5.4).

The absence of any statistically significant differences in upper limb function between the two groups with regard to shoulder girdle stability post BBS training could be attributed to both groups receiving the mandatory standard care rehabilitation during the research study. Both groups could have improved in a similar way because they were comparable regarding severity and hence little or no difference between the two groups was noted. Both groups received intensive therapy daily and hence could have benefitted more from that. No relationship could be established between the shoulder girdle stability training and the change with regard to upper-limb function.

5.6 The effect of shoulder stability training using the BBS on upper limb pain

At baseline a statistically significant difference ($p = 0.05$) was found between the control and experimental groups with regard to pain experienced by participants as measured with the WBFPRS (see Table 4.7), despite the fact that shoulder girdle stability and the severity of upper limb function were similar. This could also be due to the effect that the experimental group not experiencing any pain from baseline. This might be attributed to the small sample size. No statistically significant difference in pain experienced between the two groups was found at three and six months post-stroke.

In previous studies the prevalence of upper-limb pain varied, and the incidence of upper limb pain in some of these studies was associated with age and gender (Demirci et al., 2007; Aras et al., 2004). A study by Adey-Wakeling et al. (2013) found the incidence of post-stroke shoulder pain to be 29% over a 12-month follow-up period with the median pain score being most severe at four months. In the current study the pain incidence was highest at the one-month follow-up post-baseline with 23% of the participants indicating their experience of pain to be the worst post-stroke. The experience of pain is complex and includes the interaction of multiple factors (see Section 2.4). In this study no differences were found between the median ages of the two groups. Thus, age could not have been the attributing factor causing pain in the control group. However, it might be attributed to the gender distribution in the two groups, because the control group contained more females than males.

Owing to their primary care taker role in society, females tend to be less attentive to their own needs and health and, therefore, could have reported differently on pain and might not always recognise the severity and warning signs as early as their male counterparts (Rangell et al., 2013; Beal, 2010). Females do not seek medical assistance as quickly as males, which also could have increased the severity of the strokes they experienced (Beal, 2010; Chen et al., 2005). Previous underlying pathological conditions causing pain may become more prone post-stroke (Gilmore et al., 2004), and there may be an association between these impairments and the severity of the paresis (Lang et al., 2012; Davies, 2000). Normal aging can also lead to decreased ROM before the stroke. These symptoms may be asymptomatic, but may cause shoulder pain post-stroke (Gilmore et al., 2004). Furthermore, the muscle strength of females is less than those of males, which may make them more prone to pre-existing pathology (Sinaki et al., 2001).

Various other reasons (see Sections 2.4 and 2.5) may cause upper limb pain post-stroke, for example, reduced motor function and muscle imbalance (Kang et al., 2014; Adey-Wakeling et al., 2013; Huang et al., 2010; Lum et al., 2009). Some stroke-related factors may be a flaccid upper limb (hypotonicity) which contributes to subluxation, and capsular stretch, abnormal tone and abnormal movement patterns which contribute to rotator cuff or scapular instability (Adey-Wakeling et al., 2013; Huang et al., 2010; Paci et al., 2007). Damage to the soft tissues and shoulder could also occur during post-stroke care in hospital (Adey-Wakeling et al., 2013). When the upper limb is actively or passively moved through the normal ROM without correcting the abnormal alignment it may cause trauma and pain in the shoulder (Adey-Wakeling et al., 2013). These were not assessed in detail for purposes of this study; therefore, the researcher cannot definitively exclude any of these causes.

There is evidence that left-sided hemiplegia involves less movement and increased pain as a result of the patient's increased tendency towards visuospatial inattention and unilateral neglect, leading to the patient taking less care of the affected upper limb in the end (Demirci et al., 2007; Ratnasabapathy et al., 2003). Most post-stroke individuals with upper-limb pain have decreased motor function in the shoulder and are at risk of "learned non-use", which may prevent or limit motor recovery and, in

return, cause upper limb pain (Taub et al., 2006). In the control group were two participants with left-sided hemiplegia, and five with right-sided hemiplegia, whereas the experimental group had seven left-sided hemiplegia and three right-sided hemiplegia patients. In both groups patients' upper-limb function changed from moderate to mild impairment (see Sections 4.4 and 4.6), indicating that in this study these factors could not have been the contributing factors. Somatosensory impairments may also play a role in post-stroke upper-limb pain (Zeilig et al., 2013; Roosink et al., 2012). There was no statistically significant difference (between groups) with regard to the participants' sensation and passive joint motion when tested with the FMA-UE (see Table 4.6). Thus, for purposes of this study, pain could not be linked to somatosensory impairments.

Moreover, no statistically significant differences were found between the groups at the one-, three- and six-months' follow-up post-baseline, meaning that no direct conclusion can be drawn with regard to the effect of shoulder girdle stability training using the BBS on pain.

5.7 The effect of shoulder stability training using the BBS on HRQoL

Defining l*ife satisfaction* is a process where individuals assess the quality of their lives on the basis of their own unique set of criteria (Atif et al., 2013). In the SF-36v2 participants had to report on their own perception of the state of their general health and how it changed – the lower the score the greater their disability and the higher the score the less the disability (Atif et al., 2013; Demet et al., 2008). Participants' perception of "their health change" (as phrased according to the SF-36v2) at baseline showed that the experimental group had better scores than the control group (see Table 4.8). However, there was no statistically significance ($p = 0.47$) between the two groups in their perception of "their health change". At the one-, three- and six-months' follow-ups, post-baseline, both groups had the same values, although the experimental group's findings indicated higher mean values than the control group (though still statistically not significant).

At baseline the control group showed a statistically significant difference when reporting on the extent of the impact of emotional problems on role limitation (SF-36v2) ($p = 0.03$). The control group's findings indicated greater disability than the experimental group. Pain may play a huge role in reporting HRQoL, specifically with regard to the physical function, and may lead to depression (Lindgren et al., 2007). In this study the control group experienced more pain (see Table 4.7 and Section 5.6) which may have influenced the participants' report on the impact of emotional problems on role limitation. No consistent patterns were found with regard to differences between the control and the experimental groups in the different follow-up post-baseline periods tested.

The increase in physical function of the control group at one and three months may be attributed to them continuing with the standard therapy programme and, hence, becoming more independent after discharge – or it could be due to spontaneous recovery (see Section 5.5) (Chae et al., 2007). The less physical function patients have the more dependent they become on others for their basic needs and ADL. Even a mild impairment of upper-limb function post-stroke results in significant limitations in ADL and the fulfilment of their life roles (Rhoda et al., 2015; Rhoda et al., 2011; Mamabolo et al., 2009). The participants in both groups had similar impairment levels with regard to their upper-limb function, which could be one reason why no differences were detected in their HRQoL.

The most common activities that post-stroke patients struggle with may include washing clothes, shopping, house work and travelling by means of public transport (Hartman-Maeir et al., 2007; Rouillard et al., 2012). Studies conducted in both developed and developing countries revealed that post-stroke assistance is needed with ADL (Rhoda et al., 2011). In sub-Saharan Africa post-stroke survivors appear to be more dependent on others for care than on self-care, for example, a study found that 60% of South African post-stroke survivors needed assistance (SASPI Project Team, 2004; Walker et al., 2000). The more dependent patients become, the weaker their experience of their perceived HRQoL. Another reason for the change regarding physical function from baseline to the six-months' post-baseline follow-up could be the patients adjusting to their disability and circumstances. Increased awareness and

sensory feedback received during the shoulder stability training (see Section 2.7.3) followed by spontaneous stimulation also could have influenced the recovery process of the affected limb during functional activities (Cachupe et al., 2001). Furthermore, abnormal muscle tone could have been influenced by the weight-bearing status during the shoulder stability training (Kang et al., 2014; Lang et al., 2012; Lum et al., 2009). Although no differences were noted between the groups with regard to their perception of HRQoL, this may be a possible reason for the similar results. The aim of the study was to determine the effect of shoulder stability training using the BBS on the HRQoL, and the researcher did not measure all the above-mentioned aspects. The small sample size also could be a possible reason for not finding significant changes.

Functional tasks of the upper limb require complex integration of movement from the shoulder girdle to the hand and fingers. This is directly dependent on the return of active movement, muscle tone, ROM, sensation and proprioception, as well as planning the active movement (Kang et al., 2014; Lum et al., 2009). No consistent patterns were identified with regard to the participants' perception of HRQoL between the control and the experimental groups concerning the different dimensions. A study performed by Morris et al. (2013) on participants three months or longer post-stroke identified upper-limb function as a key predictor of reduced HRQoL and indicated that 5% to 20% of stroke survivors still experienced upper-limb dysfunction six months post-stroke. The researchers also found that decreased upper-limb function could have impacted negatively on the participants' functionality and participation in leisure activities. This is comparable with the findings of the current study: At baseline the participants in both groups indicated moderate upper-limb impairment (assessed with the FMA-UE) and greater disability in HRQoL (measured with the SF-36v2), while at one-month follow-up post-baseline they indicated mild impairment in upper-limb function and less disability in HRQoL (see Sections 4.6, 4.8 and 5.5).

At both the three- and six-months' follow-up post-baseline the participants in the experimental group reported significantly improved health from baseline (see Table 4.8). The participants in the experimental group, therefore, were more likely to have experienced better HRQoL over time post-stroke. A possible reason for this may

have been the pain experienced by the control group (see Table 4.7 and Section 5.6). This concurs with findings from previous studies reporting that pain has a negative influence on rehabilitation, which could lead to depression and decreased HRQoL (Franzén-Dahlin and Laska, 2012; Lindgren et al., 2007; Widar et al., 2004). The literature further indicates that patients who present with poor upper-limb function and pain may experience lower HRQoL because the pain limits their ADL post-stroke (Lindgren et al., 2007). Gender also could be a factor in this regard; females appear to have poorer perceived physical ability than males (Franzén-Dahlin & Laska, 2012; also see Section 2.5.1). As mentioned previously, one of the primary life roles of females is taking care of their family and if they have poor physical ability, that may affect the quality and/or quantity of their ADL and functional activities (Rangell et al., 2013; De Weerd et al., 2012). In this study, the control group had more females than the experimental group (see Section 4.4) and also experienced more pain than the experimental group, ensuing in the experimental group experiencing slightly better HRQoL.

5.8 Factors that may be associated with shoulder girdle stability

In general, this study found no factors associated with shoulder girdle stability. However, the study found a trend towards significance ($p = 0.07$) between the shoulder girdle stability of male versus female participants, with males having better shoulder girdle stability. In this study the control group consisted of more females than males and the experimental group of more males than females. This finding is comparable with the findings of previous studies reported by Botha et al. (2014) and Ferreira et al. (2015). Possible reasons for this finding may be the anatomical differences between genders and/or hormonal factors.

Shoulder girdle stability is influenced by anatomical or structural aspects of the gleno-humeral joint (see Section 2.3). Structural differences between males and females are the following: Males have greater overall stature, greater muscle and bone mass and less fat mass compared to females (Kalichman & Ratmansky, 2011; Vasavada et al., 2008). The gleno-humeral structure is influenced by gender, with males having a rounder glenoid fossa and women having a more oval glenoid fossa giving the joint

more structural stability (Kalichman & Ratmansky, 2011; Garofalo et al., 2009). Women are relatively weaker in their upper bodies, and their ligaments and joints have increased laxity (Holschen, 2004). Females also tend to have decreased joint proprioception in the shoulder in comparison with males (Algan, 2012). This may be a possible reason for the increased shoulder stability in males.

It is important to note that the small study sample (for the total study sample, but especially the three -and six- months' follow-up) could be the reason for limited findings. A bigger sample size could have provided more conclusive findings and conclusions (Glennerster &Kudzai, 2013).

5.9 Conclusion

The discussion of the findings in this chapter indicates that upper-limb weight-bearing training (using the BBS) had no effect on the HRQoL, upper-limb function, pain and shoulder girdle stability in patients with hemiplegia post-stroke (Chapter 3). The small size of the sample and the gender mix of the experimental and control groups might have caused this lack of more and clearly defined findings.

This chapter consisted of a discussion and application of the results. Chapter 6 will draw conclusions of this study, identify limitations and provide recommendations for future research.

CHAPTER 6

6. CONCLUSIONS AND RECOMMENDATIONS

The previous chapter discussed the study findings while this chapter provides the conclusions, limitations and recommendations for future research and implementation in clinical practice.

6.1 Conclusions

In this cohort of patients, shoulder stability training using the BBS did not have an effect on shoulder-girdle stability or influenced upper limb pain because no statistically significant differences were found between the control and experimental groups. The experimental group did not experience any pain. No other factors were associated with shoulder-girdle stability. Therefore, shoulder-stability training did not result in better upper-limb function and HRQoL outcomes over time.

The researcher aimed at identifying another treatment modality for the rehabilitation of the upper limb post-stroke, as this poses many challenges. Although evidence-based therapeutic modalities for and approaches to rehabilitating the upper limb post-stroke do exist, no one modality has been proven more effective than another. This study reinforced the importance of identifying and appropriately addressing shoulder-girdle instability in stroke patients.

In closing, the researcher is of the opinion that this study is of great value for the development of future physiotherapy intervention programmes using the BBS as a measurement and therapeutic tool for the upper limb. This study also provides baseline information for further research in the field of stroke and upper limb function that has not been explored.

6.2 Recommendations

Having thoroughly considered the findings of the study and the findings of studies reported in literature, a number of clinical recommendations can be made, as well as recommendations for further research in the field.

6.2.1 Clinical recommendations

Based on the final outcome and findings of the study, the researcher wishes to make the following clinical recommendation:

- The use of the BBS for the enhancement of shoulder girdle stability should be investigated over a period of at least six weeks. Studies done by Awad et al. (2015) and Mamabolo et al. (2009) both suggested that rehabilitation had positive effects when done for a minimum period of six weeks.
- The use of the BBS should be investigated with a view to enhancing shoulder girdle stability. The effect of the BBS on shoulder-girdle stability first should be explored in a bigger study sample. Even though the shoulder might not primarily function in a weight-bearing position during ADL, the benefits of including weight-bearing or modified weight-bearing positions in shoulder girdle rehabilitation cannot be ignored. The benefits for the shoulder joint and proximal shoulder-girdle stability include enhanced muscle contraction and improved joint circulation, counteracting osteoporosis.
- An awareness of possible alternative applications of the BBS beyond balance retraining and lower-limb rehabilitation was created with the supplier/agent and the therapists working at the Life Rehabilitation Unit (Pasteur Hospital) who have access to the apparatus. Alternative positioning as well as using it with other patients, for example the visually impaired, should be explored applying the same principles and the therapist compensating with facilitation and verbal feedback to achieve the proprioceptive input and the co-contraction of the muscles.

6.2.2 Recommendations for future research

From this study it became clear that more research in this specialised area is required; therefore, the following recommendations are made for further study:

- More clinical studies should be conducted with regard to using the same testing position, as well as other testing positions, which include weight bearing on the upper limb, longer testing time to compare the muscle endurance of men and women, and a larger population.
- To compensate of the loss to follow-up or to limit drop-out, it is recommended that researchers should make use of the intention-to-treat principle: all participants should be followed up and should be provided with outcomes measures; participants who withdraw or discontinue must be followed up throughout the study and their outcomes should be reported, reasons for drop-out and major deviations should be reported and researchers should provide honest feedback to the participants. Researchers should be very careful when discussing results and making assumptions. Sound planning of the methodology is of utmost importance to minimize the chance of drop-outs. Protocol, post-randomization exclusions could be appropriate if there was strict double blinding, or if the patients were not subjected to any intervention. The researcher should make use of specific, clearly identified methods to handle missing data, and try to motivate compliance (Armijo-Olivo et al., 2009).

6.3 Study limitations

Several challenges were encountered during the execution of the study. The main limitations of this study were the small sample size and the lack of representation of population-based patients, post-stroke. This can be ascribed to the fact that Life Rehabilitation Unit (Pasteur Hospital) was the only source from which the study participants were recruited. Also, the small sample size gave rise to a number of methodological and patient-specific challenges.

Although the sample size calculated (only for the shoulder girdle stability) (see Section 3.4.1.1) for this study was attained, the inclusion of more participants could have been useful in finding more statistically significant results. Only a small number (11.74%) of the participants who were screened for the purpose of the study (see Section 3.4.1.2) could be included in the study due to various reasons of exclusion (see Table 4.2). The sample was not normally distributed and was not representative of the population due to the significant number of exclusions. It is evident that a large number of stroke survivors presented with aphasia and cognitive impairment. The inclusion and exclusion criteria could not be adjusted due to the diversity of the population and the measurement tools used in this study.

Participants continued with standard care, which included an intensive rehabilitation programme in conjunction with the intervention. The testing and intervention could only be conducted after 15:00 (3 pm) (which also interfered with visiting hours, dinner and bathing), and the participants did not receive any remuneration for their participation (see Section 3.4). The research could only be conducted after 15:00 (3 pm) due to the agreement with Life Rehabilitation Unit (Pasteur Hospital) not to interfere with their standard therapy programme.

Life Rehabilitation Unit (Pasteur Hospital) is a central rehabilitation facility admitting patients from a wide geographical area for acute rehabilitation following stroke. Patients residing outside of Bloemfontein were less likely to return for follow-up due to travel and accommodation costs and caregivers losing income as they would have to accompany participants who, in most cases, were unable to drive themselves. This resulted in no physical measures being done at three and six months. The researcher was unable to establish the value of shoulder-girdle stability training on shoulder stability and upper-limb function over time. This necessitated the telephonic follow-up, allowing only for subjective measures relating to pain and HRQoL to be measured over time (see Sections 3.4 and 4.3).

Only one BBS was available for testing during the time frame of the study and participants could be tested only at a single site. The calibration of the BBS is compromised when moved; therefore, the system could not be moved to another

venue. Technical difficulties with the BBS also were experienced for a period of three weeks during the execution of the research.

6.4 Conclusion

The study posed many challenges, but created opportunities to do an investigation of the current rehabilitation methods used to assist post-stroke patients in regaining use of their upper limbs. Although no clear-cut answers have been found, it is trusted that the study will encourage therapists supporting these patients to make serious endeavours to improve patients' HRQoL and to keep on searching for methods and procedures to lessen pain. With the aid of new technology and research opportunities, the field of the rehabilitation of post-stroke patients lies fallow, and innovative rehabilitation needs to be investigated in earnest. It is believed that this study will make a contribution to finding ways to counter long-term adult disability.

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APPENDICES

Appendix A: Fugl-Meyer Assessment Upper Extremity (FMA-UE)

FUGL-MEYER ASSESSMENT UPPER EXTREMITY (FMA-UE) Assessment of sensorimotor function

ID:
Date:
Examiner:

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

A. UPPER EXTREMITY, sitting position

I. Reflex activity	none	can be elicited
Flexors: biceps and finger flexors	0	2
Extensors: triceps	0	2
Subtotal I (max 4)		

II. Volitional movement within synergies, without gravitational help			none	partial	full
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). **Extensor synergy:** Hand from ipsilateral ear to the contralateral knee	Shoulder	retraction	0	1	2
		elevation	0	1	2
		abduction (90°)	0	1	2
		external rotation	0	1	2
	Elbow	flexion	0	1	2
	Forearm	supination	0	1	2
	Shoulder	adduction/internal rotation	0	1	2
	Elbow	extension	0	1	2
	Forearm	pronation	0	1	2
Subtotal II (max 18)					

III. Volitional movement mixing synergies, without compensation		none	partial	full
Hand to lumbar spine	cannot be performed, hand in front of SIAS	0		
	hand behind of SIAS (without compensation)		1	
	hand to lumbar spine (without compensation)			2
Shoulder flexion 0°-90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion	0		
	abduction or elbow flexion during movement		1	
	complete flexion 90°, maintains 0° in elbow			2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible	0		
	limited pronation/supination, maintains position		1	
	complete pronation/supination, maintains position			2
Subtotal III (max 6)				

IV. Volitional movement with little or no synergy		none	partial	full
Shoulder abduction 0 - 90° elbow at 0° forearm pronated	immediate supination or elbow flexion	0		
	supination or elbow flexion during movement		1	
	abduction 90°, maintains extension and pronation			2
Shoulder flexion 90°- 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion	0		
	abduction or elbow flexion during movement		1	
	complete flexion, maintains 0° in elbow			2
Pronation/supination elbow at 0° shoulder at 30°-90° flexion	no pronation/supination, starting position impossible	0		
	limited pronation/supination, maintains extension		1	
	full pronation/supination, maintains elbow extension			2
Subtotal IV (max 6)				

V. Normal reflex activity evaluated only if full score of 6 points achieved on part IV				
biceps, triceps, finger flexors	0 points on part IV or 2 of 3 reflexes markedly hyperactive	0		
	1 reflex markedly hyperactive or at least 2 reflexes lively		1	
	maximum of 1 reflex lively, none hyperactive			2
Subtotal V (max 2)				

Total A (max 36)

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B. WRIST support may be provided at the elbow to take or hold the position, no support at wrist, check the passive range of motion prior testing		none	partial	full
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance is taken maintains position against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance is taken maintains position against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
	Total B (max 10)			

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
A – flexion in PIP and DIP (digits II-V) **extension in MCP II-V**	cannot be performed can hold position but weak maintains position against resistance	0	1	2
B – thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
C - opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
D – cylinder grip cylinder shaped object (small can) tug upward, opposition in digits I and II	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
E – spherical grip fingers in abduction/flexion, thumb opposed, tennis ball	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
	Total C (max 14)			

D. COORDINATION/SPEED after one trial with both arms, blind-folded, tip of the index finger from knee to nose, 5 times as fast as possible		marked	slight	none
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		> 5s	**2 - 5s**	**< 1s**
Time	more than 5 seconds slower than unaffected side 2-5 seconds slower than unaffected side maximum difference of1 second between sides	0	1	2
	Total D (max 6)			

TOTAL A-D (max 66)	

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H. SENSATION, upper extremity blind-folded, compared with unaffected side		**anesthesia**	**hypoesthesia dysesthesia**	**normal**
Light touch	upper arm, forearm palmar surface of the hand	0 0	1 1	2 2
		absence less than 3/4 correct	**3/4 correct considerable difference**	**correct 100% little or no difference**
Position small alterations in the position	shoulder elbow wrist thumb (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

J. PASSIVE JOINT MOTION, upper extremity				**J. JOINT PAIN** during passive motion, upper extremity		
Sitting position, compare with unaffected side	only few degrees (less than 10° in shoulder)	decreased	normal	pronounced constant pain during or at the end of movement	some pain	no pain
Shoulder						
Flexion (0° - 180°)	0	1	2	0	1	2
Abduction (0°-90°)	0	1	2	0	1	2
External rotation	0	1	2	0	1	2
Internal rotation	0	1	2	0	1	2
Elbow						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Forearm						
Pronation	0	1	2	0	1	2
Supination	0	1	2	0	1	2
Wrist						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Fingers						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Total (max 24)				**Total** (max 24)		

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A. UPPER EXTREMITY	/36
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/ 6
TOTAL A-D (motor function)	/66

H. SENSATION	/12
J. PASSIVE JOINT MOTION	/24
J. JOINT PAIN	/24

Appendix B: Wong-Baker FACES Pain Rating Scale

WONG-BAKER FACES FOUNDATION

Our Foundation Exists to Provide Global Access to our Scale and to Promote Optimal Pain Assessment, Pain Management, and Atraumatic Care.

Dear Heleen,

Thank you for contacting our foundation and completing the web form.

You have permission to use our scale in your research, without a licensing requirement or fee.

Please follow these four conditions:

- The information below is for your use only. We ask that you not share it with other unlicensed organizations.
- Use the authorized image of the scale provided below.
- Use the scale as the instructions indicate, without modifications.
- Do not use the scale for profit.

Here is the JPEG of the scale in English for your use: Wong-Baker FACES® Pain Rating Scale.

Afrikaans Version

Instructions for the use of the scale

Frequently Asked Questions

When you have completed your study and are submitting your manuscript for publication, please use this image that includes the necessary copyright and trademark information for publishing the research. Image for Publication-Blue Image for Publication-Black

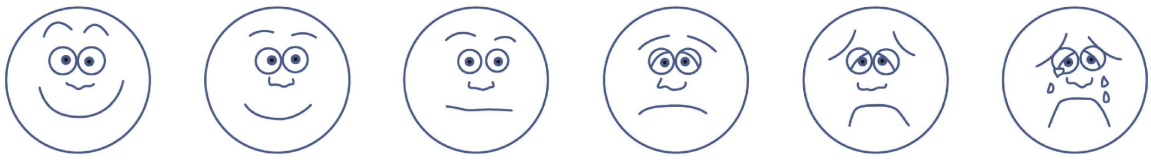
Please let me know if you need anything else, including language translations of the scale. We would love to hear about the results of your research.

Kind regards,

Connie

Connie M. Baker
Executive Director
Wong-Baker FACES Foundation
www.WongBakerFACES.org
(405) 608-8083

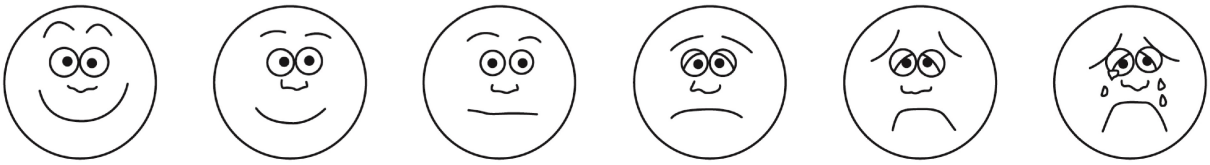
Wong-Baker FACES® Pain Rating Scale



0	2	4	6	8	10
Is nie seer nie	Is ‘n bietjie seer	Is ‘n bietjie meer seer	Is nog meer seer	Is baie seer	Is die ergste seer

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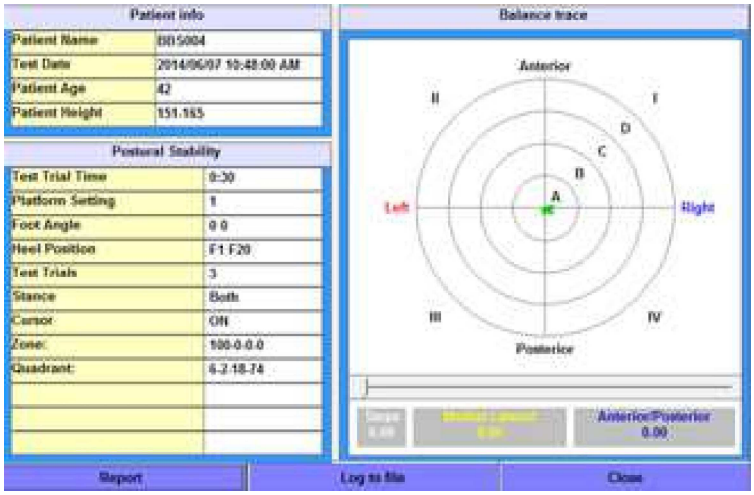
Wong-Baker FACES® Pain Rating Scale



0	2	4	6	8	10
No Hurt	Hurts Little Bit	Hurts Little More	Hurts Even More	Hurts Whole Lot	Hurts Worst

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Appendix C: Feedback Biodex Balance System



Example of a patient report from the BBS.

Appendix D: Short-Form 36 version 2 Questionnaire (SF-36v2)

Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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3 The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	<u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b	<u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d	Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e	Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g	Walking <u>more than a kilometre</u>	☐ 1	☐ 2	☐ 3
h	Walking <u>several hundred metres</u>	☐ 1	☐ 2	☐ 3
i	Walking <u>one hundred metres</u>	☐ 1	☐ 2	☐ 3
j	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

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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?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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 the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. 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 <u>past 4 weeks</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Have you had a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Have you felt worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Have you felt tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> 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
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

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U gesondheid en welstand

Hierdie vraelys handel oor u gesondheid. Die inligting sal help tred hou met hoe u voel en hoe effektief u u daaglikse take kan verrig. ***Dankie dat u hierdie vraelys voltooi!***

Merk asseblief 'n ☒ in die blokkie wat u antwoord die beste beskryf, vir elkeen van die volgende vrae.

1. In die algemeen sou u sê u gesondheid is:

Uitstekend	Baie goed	Goed	Nie baie goed nie	Swak
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>In vergelyking met een jaar gelede</u>, hoe sou u <u>nou</u> u algemene gesondheid beskrywe?

Baie beter as 'n jaar gelede	Ietwat beter as 'n jaar gelede	Omtrent dieselfde as 'n jaar gelede	Ietwat swakker as 'n jaar gelede	Baie swakker as 'n jaar gelede
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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3. Die volgende vrae hou verband met aktiwiteite wat u gedurende 'n gewone dag mag doen. Beperk u gesondheid u tans in hierdie aktiwiteite? Indien wel, in hoe 'n mate?

	Ja, baie beperk	Ja, bietjie beperk	Nee, geen beperking
a Inspannings aktiwiteite soos hardloop, swaar voorwerpe optel, deelname aan strawwe sportsoorte	☐ 1	☐ 2	☐ 3
b Matige aktiwiteite soos die skuif van 'n tafel, stoot van 'n stofsuier, vee met 'n besem, fietsry, of kegelbal.	☐ 1	☐ 2	☐ 3
c Optel of dra van kruidenierswarepakkies	☐ 1	☐ 2	☐ 3
d Die klim van 'n paar stelle trappe	☐ 1	☐ 2	☐ 3
e Die klim van een stel trappe	☐ 1	☐ 2	☐ 3
f Buk, kniel of hurk	☐ 1	☐ 2	☐ 3
g Stap meer as een kilometer	☐ 1	☐ 2	☐ 3
h Stap 'n paar honderd meter.	☐ 1	☐ 2	☐ 3
i Stap eenhonderd meter	☐ 1	☐ 2	☐ 3
j U self bad of aantrek	☐ 1	☐ 2	☐ 3

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4. Gedurende die afgelope 4 weke, hoe baie van die tyd het u enige van die volgende probleme in u werk of ander gereelde daaglikse aktiwiteite ondervind as gevolg van u fisiese gesondheid?

	Altyd	Meestal	Somtyds	Selde	Nooit
a Afname in die hoeveelheid tyd wat aan werk of ander aktiwiteite gespandeer word	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Minder uitgerig as wat u wou	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Beperk in die tipe werk of ander aktiwiteite	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Met moeite werk of ander aktiwiteite gedoen (bv. dit het meer inspanning geneem)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Gedurende die afgelope 4 weke, hoe baie van die tyd het u enige van die volgende probleme in u werk of ander aktiwiteite ondervind as gevolg van enige emosionele probleme (soos terneergedruktheid of angstigheid)?

	Altyd	Meestal	Somtyds	Selde	Nooit
a Afname in die hoeveelheid tyd wat aan werk of ander aktiwiteite gespandeer word	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Minder uitgerig as wat u wou	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Werk of ander aktiwiteite is nie so noukeurig as gewoonlik uitgevoer nie	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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6. **Gedurende die <u>afgelope 4 weke</u>, in watter mate het u fisiese gesondheid of emosionele probleme u normale sosiale aktiwiteite met familie, vriende, bure of groepe ontwrig?**

Geensins	Bietjie	Redelik	Heelwat	Uitermatig
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **Hoeveel <u>liggaamlike</u> pyn het u, gedurende die <u>afgelope 4 weke</u> ondervind?**

Geen liggaamlike pyn	Baie effens	Effens	Matige	Erg	Baie erg
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **Gedurende die <u>afgelope 4 weke</u>, hoeveel het <u>pyn</u> inbreuk gemaak op u normale werk (insluitend werk buite sowel as binne in die huis)?**

Geensins	Bietjie	Redelik	Heelwat	Uitermatig
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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9. Die onderstaande vrae handel oor hoe u gevoel het en hoe dit met u gegaan het gedurende die afgelope 4 weke. Vir elke vraag gee net een antwoord wat die beste beskryf hoe u gevoel het. Hoeveel van u tyd in die afgelope 4 weke…

	Altyd	Meestal	Somtyds	Selde	Nooit
a Het u vol lewenslus gevoel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Was u baie senuweeagtig gewees?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Het u so terneergedruk gevoel dat niks u kon opbeur nie?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Was u kalm en rustig gewees?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Het u baie energie gehad?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Het u neerslagtig en terneergedruk gevoel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Het u afgemat gevoel ?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Het u gelukkig gevoel ?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Het u moeg gevoel ?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. Hoeveel van u tyd wat aan sosiale aktiwiteite, soos kuier by familie of vriende, bestee word, is gedurende die afgelope 4 weke ontwrig deur fisiese gesondheid of emosionele probleme?

Altyd	Meestal	Somtyds	Selde	Nooit
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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11. In watter mate is <u>elk</u> van die volgende stellings vir u WAAR of ONWAAR?

	Definitief waar	Meestal waar	Weet nie	Meestal onwaar	Definitief onwaar
a	Dit wil vir my voorkom of ek geneig is om gouer siek te word as ander mense.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b	Ek is so gesond soos enige iemand wat ek ken.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c	Ek verwag dat my gesondheid gaan verswak	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d	My gesondheid is uitstekend	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Dankie dat u hierdie vraelys voltooi het!

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Appendix E: Ethical clearance – University of the Witwatersrand

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130405

NAME: (Principal Investigator)	Ms Heleena W Nel
DEPARTMENT:	Department of Physiotherapy Medical School
PROJECT TITLE:	Biodex Effect on the Upper Lim in Patients with Hemiplegia
DATE CONSIDERED:	26/04/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr W Mudzi
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 18/10/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature

21/10/2013

M130405Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix F: Ethical clearance – University of the Free State

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

Research Division
Internal Post Box G40
☎(051) 4052812
Fax nr (051) 4444359

E-mail address: StraussHS@ufs.ac.za

Ms H Strauss

2013-07-26

REC Reference nr 230408-011
IRB nr 00006240

MS HW NEL (VAN WYK)
C/O DR C JANSE VAN RENSBURG
DEPT OF PHYSIOTHERAPY
CR DE WET BUILDING
UFS

Dear Ms Nel (Van Wyk)

ECUFS NR 79/2013
PROJECT TITLE: BIODEX EFFECT ON THE UPPER LIMB IN PATIENTS WITH HEMIPLEGIA.

- You are hereby kindly informed that the Ethics Committee approved the above project at the meeting held on 23 July 2013.
- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.
- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.
- The Committee must be informed of any serious adverse event and/or termination of the study.
- All relevant documents e.g. signed permission letters from the authorities, institutions; changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).
- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

Appendix G: Permission from the Manager of Life Rehabilitation Unit (Pasteur Hospital)

PO Box 37697
Langenhovenpark
9330
February 2013

The Manager Life Rehabilitation Unit (Pasteur Hospital in Bloemfontein)

Permission to conduct study at your Rehabilitation Unit: "The effect of Biodex on shoulder girdle stability, upper limb function and pain in patients with hemiplegia."

I plan to do a research study on: "The effect of Biodex on shoulder girdle stability, upper limb function and pain in patients with hemiplegia." This research is done in fulfilment of MSc at the University of the Witwatersrand. I would like to conduct this study at your Rehabilitation Unit. At this moment the Biodex Balance System is only used for the treatment of lower extremities. Find included proposal for planned study accompanying the permission letter.

After a stroke patients may present with an initial loss of arm and/or hand function. The improvement of arm and/or hand function is often poor, and in 55%–75 % of cases is still poor after three to six months after the incident. The upper limb plays a vital role in the performance of single and bilateral handed functional activities. Improving arm and/or hand function following a stroke is critical to improve the quality of life.

The results gained by the study may be used to develop a treatment programme using the Biodex Balance System for the hemiplegic upper limb to improve shoulder girdle stability and arm and/or hand function. It may also help in reducing pain and prevention of other injuries or difficulties of the arm and/or hand following stroke. This in effect can lead to an increase of upper limb functionality as well as improvement of quality of life of patients experiencing stroke.

Participants will be pre- and post-tested during the study using feedback from the Biodex Balance System, Fugl-Meyer assessment upper extremity and the Wong-Baker FACES Pain Rating scale. Participants will be divided into three (3) groups where after they will receive nine (9) clinical interventions over a period of one year from the researcher. All clinical interventions will be the same for all participants, using specific preselected programmes on the Biodex Balance System. Each clinical intervention will be 30 minutes per patient.

Patients presenting with hemiplegia that meet the inclusion criteria will be invited to participate. Informed consent will be required after patients have been informed about the study. The study aim not cause any harm to you or hold any danger. The study will not impact on your scheduled rehabilitation, and will be viewed an additional intervention. This study would not interfere with your therapy program, therapists or quality service delivery. A roster will be compiled around the unit programme and will be made available to the staff.

The results may be requested by the participant after completion of the study and will be used for compiling a research report. Results may also be used for a scientific publication in an accredited journal. Progress reports can be sent to you on a yearly basis if required and will be forwarded to Life management and will be informed of the possibility of the results being published.

For any ethical concerns you may contact the secretariat of the ethics committee.

Thank you very much for considering this study to be conducted at your Hospital.

Kind regards,

Heleen Nel (van Wyk) (Researcher)
Cell phone: 0828293550
Tel: 051-4013296

Life Rehabilitation

National Rehabilitation office
Oxford Manor, 21 Chaplin Road, Illovo, 2196
Private Bag X13, Northlands, 2116, South Africa
Telephone +27 11 219 9620
Facsimile +27 86 686 0441
www.rehab.co.za

14 June 2013

Ms Heleen van Wyk

Request for permission to conduct research

Dear Heleen

Many thanks for the request for permission to conduct research at our Life Pasteur Rehabilitation Unit, Bloemfontein on the topic: **THE EFFECT OF SHOULDER STABILITY TRAINING ON THE UPPER LIMB FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH HEMIPLEGIA.**

Life Rehabilitation supports the development of the field of rehabilitation through evidence-based research and we have a number of ongoing research projects in our units.

I hereby grant **provisional** permission to you to access the Life Pasteur Rehabilitation Unit in order to conduct your research.

As we value patient confidentiality and their right to choose, permission is granted under the following conditions:

- Ethical clearance from the University of the Witwatersrand
- Obtaining written permission from patients to participate in the study. If a patient is in any way unable to provide consent, the appropriate family member must participate in the decision-making process
- No patient may be identified, either by name or by the unit where the patient received his/her rehabilitation.
- Access to patient documentation must be controlled and supervised
- The data gathered may only be used for the purpose of the research no information obtained in our units may be used by third parties

Access to the unit is dependent upon permission by the relevant managers to limit disruption to the unit routine and patients' rehabilitation programmes. Please liaise with the Rehabilitation Practice Manager, Ms Christina Fourie and Therapy Services Coordinator, Ms Christolene Saaiman.

Please provide a copy of ethical clearance for our records once received. I wish you success with your research, and look forward to the results. We would appreciate a copy of your research upon completion.

Sincerely,

Nina Strydom
Support Specialist
Clinical Products
Life Healthcare

Tel: +27 31 313 7912
Fax: +27 866781450
Mobile: +27 84 566 1281
Email: nina.strydom@lifehealthcare.co.za
Website: www.lifehealthcare.co.za

Appendix H: Information letter and informed consent – study participants

PO Box 37697
Langenhovenpark
9330

Dear study participant

Invitation to partake in the study: <u>"The effect of Biodex on shoulder girdle stability, upper limb function and pain in patients with hemiplegia."</u>

I plan to do a research study on: "The effect of Biodex on shoulder girdle stability, upper limb function and pain in patients with hemiplegia." This research is done in fulfilment of MSc at the University of the Witwatersrand.

You are invited to partake in this study. Your participation will be dearly appreciated and is very valuable to the researcher.

After a stroke patients may present with an initial loss of arm and/or hand function. The improvement of arm and/or hand function is often poor, and in 55%–75% of cases is still poor after three to six months after the incident. The upper limb plays a vital role in the performance of single and bilateral handed functional activities. Improving arm and/or hand function following a stroke is critical to improve the quality of life.

The results gained by the study may be used to develop a treatment programme using the Biodex Balance System for the hemiplegic upper limb to improve shoulder girdle stability and arm and/or hand function. It may also help in reducing pain and prevention of other injuries or difficulties of the arm and/or hand following stroke. This in effect can lead to an increase of upper limb functionality as well as improvement of quality of life of patients experiencing stroke.

Participants will be pre- and post-tested during the study using feedback from the Biodex Balance System, Fugl-Meyer assessment upper extremity and the Wong-Baker FACES Pain Rating scale. Participants will be divided into three (3) groups

where after they will receive nine (9) clinical interventions from the researcher. All clinical interventions will be the same for all participants, using specific preselected programmes on the Biodex Balance System.

Your participation in this study is voluntary and you may withdraw from the study at any point of time without risk of penalty. The researcher will keep your information confidential.

The study aim not to cause any harm to you or hold any danger. The study will not impact on your scheduled rehabilitation, and will be viewed an additional intervention. This study would not interfere with your therapy program, therapists or quality service delivery. No remuneration will be provided for participating. Participants may contact the researcher at any time for further information.

Your name will not be identified in the results of the study, thus you will stay anonymous in the compiling of the results. The results from this study will be used to compile a research report. The results may also be used for a scientific publication in an accredited journal.

For any ethical concerns you may contact the secretariat of the ethics committee.

Thank you very much for participating to this study.

Kind regards,

Heleen Nel (van Wyk) (Researcher)
Cell phone: 0828293550
Tel: 051-4013296

I _____ (name of participant), **agree to participate** in the following study: “The effect of Biodex on shoulder girdle stability to improve upper limb function of patients with hemiplegia.” I understand the following:

- That my participation is voluntary.
- I have the right to withdraw from the study at any point of time without reason.
- That my identity will stay confidential.
- The study aim not to cause any harm to the participant or hold any danger.
- The study would not influence other therapy/treatment negatively of the participant and is additional.
- The results will be anonymously presented in the study report and/or scientific article.
- No remuneration will be provided for my participation.
- I may contact the researcher for any additional information.
- Results may be requested by the participant after the completion of the study.
- Results will be used for compiling a research report in fulfilment of a MSc. degree at the University of the Witwatersrand.
- Results may be used for a scientific publication in an accredited journal.

Participant

_____ (Sign) at _____ (place)

on the _____ (date).

Witness

_____ (Sign) _____ (name)

_____ (date).

Appendix I: Screening checklist for inclusion

SCREENING OF STUDY POPULATION

Date

"THE EFFECT OF SHOULDER STABILITY TRAINING ON THE UPPER LIMB FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH HEMIPLEGIA."

Study population nr	Name	Age	Gender	L / R / Bilateral hemiplegia	Vision	FIM/FAM Cognition	Cognition screen	Aphasia	Other	Include/ exclude	Informed consent	Partici pant nr
SP001												
SP002												
SP003												
SP004												
SP005												
SP006												
SP007												
SP008												
SP009												
SP010												
SP011												
SP012												
SP013												

Appendix J: Demographic information sheet

"THE EFFECT OF SHOULDER STABILITY TRAINING ON THE UPPER LIMB FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH HEMIPLEGIA. "

Demographic information

Office use only

1 Participant number: ☐☐☐ ☐☐☐ 1-3

2 Adress: _____

_____

3 Telephone nr: _____

_____

4 Age of participant (years): ☐☐ ☐☐ 4,5

5 Gender: Male ☐ Female ☐ ☐ 6

6 Type of stroke: Infarct ☐ Hemorrhage ☐ Not specified ☐ ☐ 7

7 Side of body affected: Left ☐ Right ☐ ☐ 8

8 Date of stroke: ☐☐ D ☐☐ M ☐☐ Y ☐☐☐☐☐☐ 9-14
d d m m y y

9 Previous stroke: Yes ☐ No ☐ ☐ 15

10 Date of previous strokes: ☐☐ D ☐☐ M ☐☐ Y ☐☐☐☐☐☐ 16-21
d d m m y y

☐☐ D ☐☐ M ☐☐ Y ☐☐☐☐☐☐ 22-27
d d m m y y

11 Side affectected by previous stroke: Left Right ☐ 28
Left Right ☐ 29

12 Occupation: _____ ☐☐ 30,31

13 Hobbies: _____ ☐☐ 32,33

14 Additional History: (Comorbidities)

	Yes	No	
Heart disease			☐ 34
Hipertension			☐ 35
Diabetes			☐ 36
Aneurism			☐ 37
↑ Cholesterol			☐ 38
↑ salt diet			☐ 39
Use of anti-coagulants			☐ 40

Hormone therapy			41
Smoking			42
Alcohol abuse			43
Drug abuse			44
Other			45

Specify other:

_____ 46,47

_____

This questions is about previous level of functioning:

15 How many days per week do participant housework?
[ ] days per week 48

16 How much time do participant spend doing housework?
[ ] minutes per day 49

17 How many days per week do participant gardening?
[ ] days per week 50

18 How much time do participant spend doing gardening?
[ ] minutes per day 51

19 How many days per week do participant general maintenance in and around home?
[ ] days per week 52

20 How much time do participant spend doing general maintenance in and around home?
[ ] minutes per day 53

21 How many days per week do participant taking care of family?
[ ] days per week 54

22 How much time do participant spend taking care of family?
[ ] minutes per day 55

23 How many days per week do participant walk for leisure or recreation?
[ ] days per week 56

24 How much time do participant spend walking for leisure or recreation?
[ ] minutes per day 57

25 Do participant do any leisure or recreation activities?
[YES] [NO] 58

Specify:

_____

59,60

26 How many days per week do participant do leisure or recreation?

[ ] days per week — 61

27 How much time do participant spend on leisure or recreation?

[ ] minutes per day — 62

28 How much time do participant spend sitting during a day?

[ ] hours per day — 63

[ ] minutes per day — 64

29 Date admitted at rehabilitation unit:

[ ][ ] D [ ][ ] M [ ][ ] Y — [ ][ ][ ][ ][ ][ ] 65-70

d d m m y y

30 Date of discharge from rehabilitation unit:

[ ][ ] D [ ][ ] M [ ][ ] Y — [ ][ ][ ][ ][ ][ ] 71-76

d d m m y y

31 Admission FIM/FAM score: (Score range 1-7)

Total (Score range 30-210) [ ][ ][ ] — [ ][ ][ ] 77-79

Selfcare:

Eating	[ ]	[ ] 80
Grooming	[ ]	[ ] 1
Bathing/showering	[ ]	[ ] 2
Dressing upper body	[ ]	[ ] 3
Dressing lower body	[ ]	[ ] 4
Toileting	[ ]	[ ] 5
Swallowing	[ ]	[ ] 6

Communication:

Expression	[ ]	[ ] 7
Comprehension	[ ]	[ ] 8
Reading	[ ]	[ ] 9
Writing	[ ]	[ ] 10
Speech intellibility	[ ]	[ ] 11

Psychosocial

Social interaction	[ ]	[ ] 12
Emotional status	[ ]	[ ] 13
Adjustments to limitations	[ ]	[ ] 14
Use of leisure time	[ ]	[ ] 15

Cognition

Problem solving	[ ]	[ ] 16
Memory	[ ]	[ ] 17

Orientation		18
Concentration		19
Safety awareness		20

32 Treated by the following team members:

	Yes	No	
Dietician			21
Occupational therapist			22
Psychologist			23
Physiotherapist			24
Speech therapist			25

33 Dominanace: Left | | Right | | handed 26

Appendix K: Treatment logbook

“THE EFFECT OF SHOULDER STABILITY TRAINING ON THE UPPER LIMB FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH HEMIPLEGIA. ”

Treatment logbook for study participant.

Office use only

Participant number: ☐☐☐ 1-3

Date: ☐☐ D ☐☐ M ☐☐ Y ☐☐☐☐☐☐ 4-9 (d d m m y y)

Test positioning: ☐☐☐ **L** ☐☐☐ **R**

Mark applicable:

Pre-test	Rx 1	Rx 2	Rx 3	Rx 4	Rx 5	Rx 6	Rx 7	Rx 8	Rx 9
Post-test									
1	3	6							

Vital signs:

BP ☐☐☐ / ☐☐☐ ☐☐☐/☐☐☐ 10-15

Pulse ☐☐☐ ☐☐☐ 16-18

Addisional information: _____

☐☐ 19,20
☐☐ 21,22
☐☐ 22,23

General complaints: _____

☐☐ 26,27
☐☐ 28,29
☐☐ 29,30

Information from team members: _____

☐☐ 33,34
☐☐ 35,36
☐☐ 37,38
☐☐ 39,40

Appendix L: Summary of RCTs

Appendix L: Summary of RCT's

Constraint-induced movement therapy for upper extremities in people with stroke (Review) CIMT

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age** Mean age (SD):
Alberts, 2004	10 participants: 5 intervention, 5 control	Yes	Arm motor function: WMFT Arm motor impairment: FMA, grip/force	score of < 24 on the MMSE, physician-determined major medical problems that would interfere with participation	intervention group: 65 (8.2) years, control group: 63.4 (15.5) years
Atteya, 2004	6 participants: 2 intervention, 2 control, 2 no treatment	Yes	Arm motor function: ARAT, WMFT2 Perceived arm motor function: MAL Arm motor impairment: FMA	significant cognitive impairment, haemorrhagic lesion, significant spasticity, significant pain of the upper limb	intervention group: 55 (2.8) years, control group: 52 (4.2) years, no treatment group: 56 (15.5) years
Azab, 2009	37 participants: 20 intervention, 17 control	Yes	ADL measure: BI	severe cognitive disabilities	56 (9.9) years for all participants
Bergheim, 2010	4 participants: 2 intervention, 2 control	Yes	Arm motor function: BLMA, WMFT • Everyday motor function: MAS	cerebral haemorrhage, prior stroke, unstable medical status, second cerebral diseases that were difficult to differentiate from a stroke, and previous illness/ injury that significantly impaired	intervention group: 70.5 (13.4) years, control group: 76.5 (4.9) years

				function in arms	
Boake, 2007	23 participants: 10 intervention, 13 control	Yes	Perceived arm motor function: MAL • Dexterity: GPT • Arm motor impairment: FMA2 • Neurophysiological test: TMS	not reported	intervention group: 63.1 (14.3)years, control group: 58.9 (14) years
Brogårdh, 2009	24 participants: 12 intervention, 12 control	Yes	Everyday arm motor function: MAS2 • Hand Function: SHFT • Perceived arm motor function: MAL	deformity of the more affected arm due to previous injury, drug abuse, epilepsy, mental disorder and botulinum toxin injections for spasticity treatment	intervention group: 58.5 (6.3) years, control group: 56.7 (10.5) years
Brunner, 2012	30 participants: 14 intervention, 16 control	Yes	Arm motor function: ARAT • Dexterity: 9HPT	additional neurological diseases, unstable medical conditions, musculoskeletal disorders affecting arm mobility and severe cognitive impairment	61 (10) years, control group: 64.8 (12.8) years
Dahl, 2008	30 participants: 18 intervention, 12 control	Yes	Motor function: WMFT • Perceived arm motor function: MAL • ADL measure: FIM2 • Quality of life: SIS	presence of other neurological diseases, unstable cardiovascular disease, severe depression (> 12 points on Montgomery and Aasberg Depression Rating Scale), marked neglect (line bisection more than 2 cm over the midline), life expectancy < 6	intervention group: 62 (8) years, control group: 60 (12) years

				months, sequel from a previous stroke and clinically evaluated insufficient endurance to participate	
Dromerick, 2000	20 participants: 11 intervention, 9 control	Yes	Motor function: ARAT Measures post-treatment only • ADL measure: BI, FIM	no upper extremity injury or conditions that limited use before the stroke	intervention group: 61.5 (13.7) years, control group: 71.4 (5.3) years
Dromerick, 2009	52 participants: 35 intervention, 17 control	Yes	Overall stroke severity: NIHSS • Arm motor function: ARAT • ADL measure: FIM • Quality of life: SIS (only at post-treatment) • Pain at shoulder: Wong-Baker Faces Scale • Depression: Geriatric Depression-15 Scale	inability to give informed consent; clinically significant fluctuations in mental status within 3 days of enrolment; not independent prior to stroke; hemi-spatial neglect; sensory loss; not expected to survive 1 year due to other illnesses	intervention group: 63.6 (14.38) years, control group: 64.7 (14.6) years
Hammer, 2009	30 participants: 15 intervention, 15 control	Yes	Arm motor impairment: FMA, grip/force • Spasticity: MASh • Dexterity: 16HPT • Everyday arm motor	no severe cognitive impairment (score of 20 points in the MMSE); ability to understand and follow instructions	intervention group: 66.3 (10.3) years, control group: 60.4 (11.1) years

			function: MAS		
Hayner, 2010	12 participants: 6 intervention, 6 control	Un-blinded outcome assessor	Arm motor function: WMFT • Global function: COPM	inability to refrain from smoking (because a smoking area was unavailable), inability to tolerate a regular diet (because making lunch was a part of the therapeutic design)	intervention group: 54 (11.62) years, control group: 559.5 (11.77) years
Huseyinsi-noglu, 2012	24 participants: 13 intervention, 11 control	Yes	ADL measures: FIM Arm motor function: WMFT • Perceived arm motor function: MAL 3 • Arm performance after stroke: MESUPES	no serious cognitive disorders; no excessive pain that would interfere with the ability to participate in the treatment; no excessive spasticity in any joint of the affected arm	49.1 (13.7) years, control group: 48.2 (15.4) years
Khan, 2011	42 participants: 13 intervention, 14 control, 15 therapeutic climbing	Yes	Arm motor function: WMFT • Perceived arm motor function: MAL • Shoulder pain: CMII (subscale for shoulder pain)	shoulder pain, other neurological disorders or other serious co-morbidities	intervention group: 60.4 (16.1) years, control group: 60.4 (14.8) years, therapeutic climbing 62.2 (13.5) years
Kim, 2008	17 participants: 9 intervention,	Blinding of outcome	Arm motor function: MFT • Dexterity: Purdue	balance problems, severe visual impairments, cognitive deficits and aphasia	intervention group: 51.7 (9.5) years, control group: 59.6

	8 control	assessor not reported	Pegboard Test • Perceived arm motor function: MAL		(10.3) years
Krawczyk, 2012	47 participants: 24 intervention, 23 control	Yes	Arm motor function: RMAAS • Perceived arm motor function: MAL	permanent use of the involved arm in life situations and coexisting lack of well-defined treatment goals by the patient; excessive pain, spasticity or ataxia; presence of a severe or uncontrolled medical condition; orthopaedic or neurological limitations prior to the stroke that could affect outcome; bilateral or brainstem stroke	intervention group: 48 (14) years, control group: 46 (13) years
Lin, 2007	32 participants: 17 intervention, 15 control	Yes	Perceived arm motor function: MAL • Global function measure: FIM2 • Kinematic variables	history of stroke or other neurological, neuromuscular or orthopaedic disease	intervention group: 57.11 (18.3) years, control group: 58.77 (15.5) years
Lin, 2009a	60 participants: 20 intervention, 20 control, 20 bilateral arm training group	Yes	Arm motor impairment: FMA • Activities of daily living measure: FIM • Perceived arm motor function: MAL • Quality of life: SIS	not reported	intervention group: 55.28 (9.34) years, control group: 58.77 (15.5) years, bilateral arm training group 51.58 (8.67) years

Lin, 2010	13 participants: 5 intervention, 8 control	Blinding of outcome assessor not reported	Arm motor impairment: FMA • Perceived arm motor function: MAL • Functional magnetic resonance (fMRI) measures	not reported	intervention group: 46.04 (26) years, control group: 51.06 (12.4) years
Myint, 2008	43 participants: 23 intervention, 20 control	Yes	Motor function: functional test for hemiparetic upper extremity, ARAT • Perceived arm motor function: MAL • Dexterity: 9HPT • ADL measure: modified BI	severe aphasia, high risk of fall, cerebellar stroke and severe shoulder pain affecting therapy	intervention group: 63.4 (13.6) years, control group: 63.9 (12.2) years
Page, 2001	6 participants: 2 intervention, 2 control, 2 no treatment	Yes	Arm motor function: ARAT, WMFT2 • Perceived arm motor function: MAL • Arm motor impairment: FMA	severe cognitive impairment, excessive spasticity and pain	intervention group: 55 (4.24) years, control group: 52 (5.65) years, no intervention group 60.5 (23.33) years
Page, 2002b	14 participants: 4 intervention, 5 control, 5 no treatment	Yes	Motor function: ARAT • Perceived arm motor function: MAL • Arm motor impairment: FMA	severe cognitive impairment, excessive spasticity and pain	intervention group: 73.5 (6.35) years, control group: 67.4 (13.8) years, no intervention group 68.2 (14.13) years

Page, 2004	17 participants: 7 intervention, 4 control, 6 no treatment	Yes	Arm motor function: ARAT • Perceived arm motor function: MAL • Arm motor impairment: FMA	severe cognitive impairment, excessive spasticity and pain	intervention group: 54.6 (12.77) years, control group: 60.75 (13.6) years, no intervention group 63.6 (9.81) years
Page, 2005b	10 participants: 5 intervention, 5 control	Yes	Arm motor function: ARAT • Perceived arm motor function: MAL • Arm motor impairment: FMA	severe cognitive impairment, excessive spasticity and pain	intervention group: 58.6 (6.35) years, control group: 62.2 (10.3) years
Page, 2008	35 participants: 13 intervention, 12 control, 10 no treatment	Yes	Arm motor function: ARAT • Perceived arm motor function: MAL • Arm motor impairment: FMA	severe cognitive impairment, excessive spasticity and pain	57.9 (8.4) years for all groups
Ploughman, 2004	23 participants: 10 intervention, 13 control	Blinded outcome assessor only on admission	Arm motor function: ARAT • Arm motor impairment: CMII for arm, hand, postural control and shoulder pain, grip strength	evidence of cognitive impairment	intervention group: 57.8 (10.65) years, control group: 61.62 (5.68) years

		to treatment	• ADL measure: FIM3		
Singh, 2013	40 participants: 20 intervention, 20 control	Un-blinded outcome assessor	Arm motor function: WMFT • Arm motor impairment: FMA • Spasticity: MASh (only at baseline)	severe aphasia, severe shoulder pain affecting therapy or any comorbid condition that could limit upper extremity function	intervention group: 55.2 (9.27) years, control group: 21.9 (20.51) years
Smania, 2012	66 participants: 34 intervention, 32 control	Yes	Arm motor function: WMFT • Perceived arm motor function: MAL • Spasticity: MASh	severe cognitive impairment, amount of use ≥ 2.5 on the MAL	intervention group:63.93 (9.56) years, control group: 68.25 (12.68) years
		Yes			
Suputtitada, 2004	69 participants: 36 intervention, 33 control	Yes	Arm motor function: WMFT • Perceived arm motor function: MAL • Motor impairment: ARAT	balance problems; severe aphasia; sensory disorder; severe cognitive impairments	intervention group: 60.1 (4.8) years, control group: 58.7 (4.2) years
Tariah, 2010	18 participants: 10 intervention, 8 control	Yes	Arm motor function: WMFT • Perceived arm motor function: MAL • Arm motor impairment: FMA	cognitive impairment; amount of use ≥ 2.5 on the MAL; excessive spasticity and pain	intervention group: 54.8 (10.9) years, control group: 60.6 (4.9) years

Taub, 1993	9 participants: intervention 4, control 5	Yes	Motor function: AMAT, EMF • Perceived arm motor function: MAL2	balance problems, extensive use of the affected arm, cognitive deficits, medical problems, > 75 years of age, left dominance or left hemiplegia	intervention group: 65 years, control group: 63 years
Treger, 2012	28 participants: 9 intervention, 19 control	Yes	ADL measures: FIM • Hand function: MFT • Overall stroke severity: NIHSS	neurological or orthopaedic disorders prohibiting the use of the paretic arm, neglect, apraxia, and cognitive disorders impeding collaboration	intervention group: 62 (28.4) years, control group: 61.5 (8.4) years
		Yes			
Van Delden, 2013	60 participants: 22 intervention, 19 control, 19 bilateral arm training with rhythmic auditory cueing	Blinding of outcome assessor not reported	Arm motor function: ARAT • Dexterity: 9HPT • Motor impairment: FMA, MI • Perceived arm motor function: MAL • Sensory: EmNSA • Quality of life: SIS	upper-limb orthopaedic limitations; cognitive impairment	intervention group: 59.8 (13.8) years, control group: 56.9 (12.7) years, bilateral arm training with rhythmic auditory cueing 62.6 (9.8) years
Wang, 2011	30 participants: 10 intervention, 10 control high-intensity, 10 control low-intensity	Yes	Arm motor function: WMFT	excessive pain in the affected limb; aphasia; cognitive impairment	intervention group: 59.4 (10.89) years, control group high-intensity: 63.5 (9.63) years, control group control low-intensity: 67 (7.45) years

Wittenberg, 2003	16 participants: 9 intervention, 7 control	Yes	Arm motor function: WMFT • Perceived Arm motor function: MAL • Neurophysiologic test: AMPS, PET, TMS	not reported	intervention group: 65 (41-81) years, control group: 63 (50-75) years
Wolf, 2006	222 participants: 106 intervention, 116 control	Yes	Motor function: WMFT • Perceived arm motor function: MAL • Quality of life: SIS	scored less than 24 on the MMSE; physician-determined medical problems could interfere with participation; excessive pain of the paretic extremity; substantial use of the paretic arm in daily life as determined by a score ≥ 2.5 on the Motor Activity Log	intervention group: 61 (13.5), control group: 63.43 (12.6) years
Wu, 2007a	30 participants: 15 intervention, 15 control	Yes	Perceived arm motor function: MAL • ADL measure: FIM • Kinematic variables	balance problems sufficient to compromise safety when wearing the study's constraint device; excessive spasticity in any joint of the affected upper extremity	intervention group: 54.66 (8.63) years, control group: 53.31 (6.29) years
Wu, 2007b	47 participants: 24 intervention, 23 control	Yes	Arm motor impairment: FMA • Perceived arm motor function: MAL • ADL measure: FIM • Kinematic variables	balance problems sufficient to compromise safety when wearing the study's constraint device	intervention group: 53.93 (11.2) years, control group: 56.77 (12.9) years

Wu, 2007c	26 participants: 13 intervention, 13 control	Yes	Perceived arm motor function: MAL • Arm motor impairment: FMA • ADL measure: FIM • Quality of life: SIS	balance problems sufficient to compromise safety when wearing the study's constraint device	71.44 (6.42) years, control group: 71.94 (16.79) years
Wu, 2011	66 participants: 22 intervention, 22 control, 22 BAT group	Yes	Arm motor function: WMFT • Perceived arm motor function: MAL • Kinematic variables	not reported	intervention group: 51.91 (11.93) years, control group: 55.19 (2.5) years, bilateral arm training group 52.22 (10.72) years
Wu, 2012a	57 participants: 19 intervention, 18 control, 20 arm plus trunk restraint	Yes	Arm motor function: ARAT • Perceived arm motor function: MAL • Perceived instrumental ADL participation: FAI • Quality of life: SIS	not reported	intervention group: 56.3 (12.2) years, control group: 58.6 (11.6) years, arm plus trunk restraint group 54 (9.7) years
Yoon, 2014	26 participants: 9 intervention, 9 control, 8 arm restraint plus mirror therapy	Yes	Arm motor function: WMFT • Dexterity: 9HPT, Box and Block Test • Motor impairment: grip force • Activities of daily living measure: BI (Korean version)	depression; inability to co-operate in the treatment; inability to perform the active task training for musculoskeletal problems; spasticity; complex regional pain syndrome or secondary adhesive capsulitis	intervention group: 64.33 (8.54) years, control group: 60.56 (16.94) years, arm restraint plus mirror therapy group 47.36 (14.4) years

			• Arm motor impairment: FMA • Brunnstrom stage		

(Corbetta et al., 2015)

Hands-on therapy interventions for upper limb motor dysfunction following stroke (Review)

Author	Number of participants	Blinded assessor	Outcome measures	Exclusion	Age
Carey, 1990	24	Not stated	JMTT, FTT		able-bodied group 51.5; experimental group 53.7; control group 57
Mann, 2005	22	Not stated	ARAT (Lyle 1981) and 2-point discrimination		experimental group: 68, control group: 71
Mikulecka, 2005	40	Not stated	Jebson-Taylor Test (Jebson 1969), Visual Ranking Score for Hand Function Test		experimental group: 65, control group: 69

(Winter et al., 2011)

Effects of robot-assisted therapy on stroke rehabilitation in upper limbs: Systematic review and meta-analysis of the literature.

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age**
Fazekas et al., 2007	30	Yes	F-M (s/e), FIM (self-care)		Experimental: 56.6 ±(28–82) Control: 55.9 ± (28–77)
Housman et al., 2009	28	Yes	F-M (UL)		Experimental:54.2 ±11.9 Control:56.4 ± 12.8
Kahn et al., 2006	19	Yes	Ch-McM (arm)		Experimental:55.6 ± 12.2 Control:55.9 ± 12.3
Lum et al., 2002	27	Yes	F-M (UL), FIM (self-care)		Experimental:63.2 ± 3.6 Control:65.9 ± 2.4
Lum et al., 2006	16	Yes	F-M (UL), FIM (self-care), MSS, MPS		Experimental:62.3 ± 2.8 Control:69.8 ± 4.0 Experimental:72.2 ± 11.7 Control:59.9 ± 5.5
Masiero et al., 2007	35	Yes	F-M (s/e/c, w/h), FIM (self-care)		Experimental:63.4 ± 11.8 Control:68.8 ± 10.5
Aisen et al., 1997	20	Yes	F-M (UL), FIM (self-care), MSS, MPS		Experimental:58.5 ± 8.3 Control:63.3 ± 10.6
Volpe et al., 1999	12	Yes	F-M (s/e/c, w/h), FIM (self-care),		Experimental:54 ± 7.3 Control:66 ± 4.9

			MSS, MPS		
Volpe et al., 2000	56	Yes	F-M (s/e/c, w/h), FIM (motor), MSS, MPS		Experimental:62 ± 11 Control:67 ± 10.2
Volpe et al., 2008	21	Yes	F-M (s/e/c, w/h), MPS		Experimental:62 ± 3 Control:60 ± 3
Rabadi et al., 2008	20	Yes	F-M (UL), FIM (motor), MSS, MPS		Experimental:79.5 ± 6.2 Control:67.8 ± 12.7
Lo et al.,2010	99	Yes	F-M (UL)		Experimental:66 ± 11(44–95) Control:64 ± 11(28–86)

(Norouzi-Gheidari et al., 2012)

Does Provision of Extrinsic Feedback Result in Improved Motor Learning in the Upper Limb Post stroke? A Systematic Review of the Evidence.

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age**
Winstein et al., 1999	40	No			
Cirstea et al., 2006	37	Yes			
Cirstea et al., 2007	28	Yes			

Piron et al., 2005	50	Not stated			
Jang et al., 2005	10	Yes			
Gilmore et al., 2007	10	Yes			
Maulucci et al., 2001	16	No			
Coote et al., 2008	20	Yes			
Dancause et al., 2002	10	Not stated			

(Subramanian et al., 2010)

The impact of bilateral therapy on upper limb function after chronic stroke: a systematic review

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age**
Chang et al., 2007	20	Yes			57 (14)
Hesse et al., 2003	12	Yes			64
Luft et al.,	21	Yes			62 (13)

2004					
McCombe-Waller & Whitall, 2004	20	Yes			
McCombe-Waller & Whitall, 2005	22	Yes			59 (17) 64 (10)
Richards et al., 2008	14	Yes			64
Stinear et al., 2008	32	Yes			55
Summers et al., 2007	12	Yes			62 (14)
Whitall et al., 2000	14	Yes			64

(Latimer et al., 2009)

Virtual Reality Therapy for Adults Post-Stroke: A Systematic Review and Meta-Analysis Exploring Virtual Environments and Commercial Games in Therapy.

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age**
Broeren, 2008	22	Yes			44-85
Cho, 2013	14	Yes			64.85

Cikajlo, 2012	26	Yes			58.50
Crosbie, 2012	18	Yes			60.35
da Silva Cameirao, 2011	16	Yes			61.37
Gil-Go´ mez, 2011	17	Yes			47.45
In, 2012	19	Yes			63.97
Jung, 2012	21	Yes			62.05
Katz, 2005	19	Yes			62.85
Kihoon, 2012	29	Yes			63.85
Kim, 2009	24	Yes			52.09
Kim, 2012	20	Yes			48.15
Kiper, 2011	80	Yes			64.00
Kwon, 2012	26	Yes			57.54
Lam, 2006	36	Yes			71.37
Mirelman, 2010	18	Yes			62.00
Piron, 2007	38	Yes			61.50
Piron, 2009	36	Yes			65.20
Piron, 2010	47	Yes			60.50

Saposnik, 2010	18	Yes			61.30
Subramanian, 2013	32	Yes			61.00
Yang, 2008	20	Yes			58.17
Yavuzer, 2008	20	Yes			61.10 You, 2005
You, 2005	10	Yes			57.10

(Lohse et al., 2014)

Bimanual isometric force control: Asymmetry and coordination evidence post stroke

Author	**Number of participants**	**Blinded assessor**	**Outcome measures**	**Exclusion**	**Age**
	10	Not stated	Fugl-Meyer Assessment (FMA) Modified Ashworth Scale. For control participants, hand dominance was determined by the Edinburg Handedness Inventory	presence of any additional neurological or musculoskeletal disorder, (2) a history of surgery involving either or both upper limbs, (3) uncorrected vision or hearing impairments, (4) neglect or aphasia, and (5) orthopedic injury or pain.	64.87 ± 8.07 66.66 ± 9.36 (control)

(Lodha et al., 2012)

Combined Bracing, Electrical Stimulation, and Functional Practice for Chronic, Upper-Extremity Spasticity

Author	Number of participants	Blinded assessor	Outcome measures	Exclusion	Age
	2	Yes			

(Hardy et al., 2010

Effect of position feedback during task-oriented upper-limb training after stroke: Five-case pilot study

Author	Number of participants	Blinded assessor	Outcome measures	Exclusion	Age
	5	Yes	subscale, the Motricity Index (MI), the Action Research Arm Test (ARAT), circular arm movements, and isometric strength.		

(Molier et al., 2011)

Enhancing the mirror illusion with transcranial direct current stimulation

Author	Number of participants	Blinded assessor	Outcome measures	Exclusion	Age
	12	Yes			

(Jax et al., 2015)

Recovery of submaximal upper limb force production is correlated with better arm position control and motor impairment early after a stroke

Author	Number of participants	Blinded assessor	Outcome measures	Exclusion	Age
	10	Yes			

(Turner et al., 2012)

Summary

Authors	Years	Number of minimum participants	Number of maximum participants	Number of average participants
Corbetta D, Sirtori V, Castellini G, Moja L, Gatti R; 2015 (42 studies)	1993-2014	4	222	35
Winter J, Hunter S, SimJ, Crome P; 2011 (3 studies)	1990-2005	22	40	28
Norouzi-Gheidari, N., Archambault, P.S., Fung, J.; 2012 (12 studies)	1997-2010	12	99	32
Subramanian, S.K., Massie, C.L.,	1999-2007	10	50	26

Malcolm, M.P., Levin, M.F.; 2010 (8 studies)				
Latimer, C. P., Keeling, J., Lin, B., Henderson, M., Hale, L.; 2009 (9 studies)	2000-2008	12	32	18
Lohse, K. R., Hilderman, C.G. E., Cheung, K.L., Tatla, S., Van der Loos, M.H. F.; 2014 (24 studies)	2005-2013	10	80	26

Authors	**Year**	**Number of participants**	**Blinded assessor**	
Lodha et al.	2012	10	Yes	
Hardy et al.	2010	2		
Molier et al.	2011	5		
Jax et al.	2015	12		
Turner et al.	2012	10		