CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

This chapter describes the process that was followed during this study to achieve the results presented in the following chapter. It follows a logical sequence from the selection of the study design, ethical approval, selection of subjects and location of the study to a description of the procedure to be followed, measurement and finally the proposed method of analyzing the results.

3.2 ETHICAL CLEARANCE

Prior to the commencement of this study ethical clearance was obtained from the Committee for Research on Human Subjects at the University of the Witwatersrand (Clearance number: M020509 (Appendix A).

3.3 STUDY DESIGN

This is a descriptive study of the walking ability and walking capacity of a cohort of individuals following stroke in the Soweto community.

3.4 LOCATION

This study was conducted at Chris Hani Baragwanath Hospital ,Soweto.

3.5 SAMPLE SELECTION

Consecutive patients admitted to the medical admissions ward of Chris Hani Baragwanath Hospital during the period from 27 August 2003 to 23 March 2004 with a provisional diagnosis of cerebrovascular accident (CVA) or stroke were screened for admission into the study.

It was calculated that a sample size of 58 subjects was required to detect a shortfall of at least 50 m of the actual 6MWT relative to the distance calculated using the ten-metre walk test (Dean et al 2001).

3.6 INCLUSION CRITERIA

Participants were invited to join the study if they:

- had a diagnosis of first ever CVA (resulting in hemiplegia),
- were between 40 to 80 years (these ages were chosen because they conformed with those used in the development of the reference equations by Enright and Sherrill 1998)
- were of either gender
- lived in Soweto

3.7 EXCLUSION CRITERIA

- any medical condition that would prevent them being able to perform the tests e.g. dementia, severe arthritis, severe unstable hypertension
- unable to give informed consent e.g receptive aphasia.
- People living on the outskirts of Soweto (Ennerdale, Orange Farm, Grasmere) were excluded as the transport costs would compromise their involvement in the study.

The following tables illustrate how the final sample was selected:

Table 3.1: **Illustration of initial subject selection**

Subjects	n
List of consecutive patients between 27/08/2003 and 23/03/2004 given a provisional diagnosis of stroke/CVA from the CHB Medical Admissions Ward	n

Table 3.2: **Illustration of the first screening of the initially selected subjects in destination medical ward**

	Included % (n)	**Excluded % (n)**
1. Not found in wards		% (n)
2. Aged between 40-80 years	% (n)	
▪ Aged < 40 years		% (n)
▪ Aged > 80 years		% (n)
▪ No record of age		% (n)
3. Not Soweto resident		% (n)
4. Confused		% (n)
5. Discharged before being seen		% (n)
6. Patients with a non stroke diagnosis		% (n)
7. Patients not accounted for		% (n)
Total patients after the above exclusions	**% ()**	% (n)

Table 3.3: **Illustration of second screening**

Subjects n	**Included**	**Excluded**
Telephonic or home visit confirmation of alternate diagnosis		n
Did not return, no confirmed diagnosis, Unable to find at address		n
Died, unable to confirm cause of death		n
No diagnosis of stroke, returned for clinical test 2		n
Confirmed diagnosis, did not return for clinical test 2		n
Study Group	**n**	

3.8 INSTRUMENTATION

- Scale for height in metres/centimetres and weight in kilogrammes/grammes
- Polar heart rate monitor
- Sanji 1000 1/100 second stopwatch
- Measured ten metre walkway, indoor
- Measured twenty five metre walkway, indoor
- Tape measure – 20 metre industrial, plasticized, in centimeter/metre increments
- Chair – plastic, with armrests (to rest between tests, and as a safety precaution)

3.9 MEASUREMENT TOOLS AND MEASUREMENT DOMAINS

Table 3.4: **Measurement Tools and Measurement Domains**

Measurement Tool	Domain
Barthel Index (BI) *See Appendix 10*	Activity limitation/ disability
Ten-metre walk test *See Appendix 7*	Mobility Mixed impairment /activity
2 Minute Walk Test (2MWT) *See Appendix 8*	Mobility and endurance Mixed impairment /activity
6 Minute Walk test (6MWT) *See Appendix 8*	Mobility and endurance Mixed impairment /activity
Heart Rate (HR) *See Appendix 9*	Impairment
Questionnaire *See Appendix 4*	Mixed impairment/activity

3.10 PROCEDURE

3.10.1 Screening Test

Subjects listed in terms of sample selection 3.4 were followed up in the wards by the research assistant within five days of admission. The night count book in the relevant ward was first checked to confirm the patient's admission. The subjects were excluded if they were not within the age group 40-80 years and resident in

Soweto or had already been discharged. If the patient was not confused and had a confirmed diagnosis of stroke or there was a likely presumption of stroke the research assistant explained the informed consent form to subjects (in his/her own language). Confidential patient details (Appendix 3) were confirmed including contact telephone numbers. Verbal consent was given to participate in the study.

3.10.2 **Clinical Assessment**

3.10.2.1 Clinical Test 1

The research assistant completed the initial BI immediately after the screening test. Each subject was then given an appointment card detailing the date and time for a follow-up appointment within twelve to sixteen weeks at the Chris Hani Baragwanath Hospital physiotherapy department. Contact details of the researchers were included. If available the patient's notes, discharge summary and the ward admission and discharge summary register were checked to confirm the diagnosis of stroke of all subjects prior to discharge.

3.10.2.2 Clinical Test 2

If telephone contact details were available subjects were contacted to remind them about their appointment for the walking tests. The subjects were met at the Chris Hani Baragwanath hospital physiotherapy department by the researchers and the patient's diagnosis was confirmed from their discharge summary documents. The subjects were taken by wheelchair to the testing area, a quiet internal passage where a 25 metre walkway had been marked out with tape on the floor.

The ten metre walk test was performed first. The test was first described and demonstrated by the researchers then performed by the subject. During the fifteen minute rest between tests the subject's height and

weight were measured and recorded and the Barthel Index and questionnaire (*Appendix 4)* were completed by the research assistant. The subjects were fitted with the heart rate monitor.

The 2MWT and 6MWT were then tested after an explanation of the process by the researchers. Distance walked was marked on the floor after two and six minutes respectively using masking tape on which the patient's study number was written and 2MWT/6MWT and number of laps completed. Resting heart rate was measured immediately prior to the start of the test and at exactly six minutes, the end of the 6MWT. The distance was then measured by the researcher for the 2 MWT and the 6MWT.

All the subjects who returned for testing had the opportunity to discuss any rehabilitation related issues with the researchers and were paid R10 towards their traveling costs. The subjects were then taken back to the physiotherapy department in a wheelchair.

3.11 MEASUREMENTS

Variables measured were:

- The Barthel Index was measured at the initial test and at the second test (Collin et al 1988).
- The time taken to walk ten metres was measured with a stop watch (Watson 2002).
- The distance walked in two minutes and six minutes was measured in centimeters using a tape measure (Dean et al 2001; Rossier and Wade 2001).
- Resting heart rate and heart rate after six minutes walking were measured using a Polar heart rate monitor (Macko et al 1997; Dawes et al 2003).

Normal walking speed was calculated from the ten-metre walking test results. The distance a subject would have covered in two minutes and six minutes at normal walking speed was then calculated (gait speed multiplied by two or six minutes) .

3.12 STATISTICAL ANALYSIS

Descriptive statistics ie, means and standard deviations were used to summarize the results of the variables measured. Barthel Index measures at Clinical test 1 and Clinical test 2 were compared using paired sample t-tests. Actual distance walked in six minutes and distance predicted by the ten metre speed were compared using paired sample t-tests as were the results of the two minute and six minutes walk tests respectively. Testing was done at the 0.05 level of significance.

To assess the level of disability associated with poor walking endurance after stroke, actual distance walked in six minutes and the distance predicted by the normative equations (Enright and Sherrill 1998) were compared with each other using paired sample t-tests. The equations were six minute distance for males (m) = (7.57 x height cm) – (5.02 x age) – 1.76 x weight kg) – 309m and six minute distance for females (f) = 2.11 x height cm) – (2.29 x weight kg) – (5.78 x age) + 667 m (Enright and Sherrill 1998).