CHAPTER 3

STUDY DESIGN AND METHODOLOGY

3.1 Introduction

In Chapter 3 a detailed account is given on how the research was performed. This account of the research process includes the research setting, the recruitment of participants, the matching and allocation of participants, the research process and the assessment procedure of participants from Group 1 that received visual scanning exercises integrated with task-specific activities and participants from Group 2 that received task-specific activities alone.

3.2 Ethical approval

Ethical approval to conduct this study was granted by the Ethics Committee of the Faculty of Health Sciences at the University of Pretoria (S33/2009) (Addendum 1).

3.3. Research funding

Research funding to conduct the study was obtained from the Medical Research Council of South Africa.

3.4. Research setting

The study was conducted at the Tshwane Rehabilitation Centre (TRC) in Pretoria, Gauteng, South Africa. It is a public rehabilitation centre setting, but also an academic hospital facility where research is being conducted in different fields of

healthcare. A close working relationship exists between the TRC, Steve Biko Academic Hospital and the University of Pretoria (UP). The Department of Physiotherapy, Faculty of Health Sciences at UP places students at this facility as part of their mandatory clinical blocks. Rehabilitation at this facility is conducted in a multi-disciplinary team approach consisting of physiotherapists, occupational therapists, speech-and-language therapists, dieticians, social workers, nursing staff and doctors. The facility caters for all patients using the public healthcare facilities in need of rehabilitation, including neurological conditions such as stroke, multiple sclerosis, Guillian Barre syndrome, neuropathies, spinal cord injuries as well as head injuries. Patients are referred by a large number of acute healthcare settings, including private and public facilities. Assessment of every patient is done after admission to determine the type and frequency of therapy needed. In-patients receive therapy on a daily basis according to their needs.

3.5. Study design

The study design entailed a matched-pair randomised controlled trial (Chan, Chan & Au, 2006) performed at the TRC. The research approach therefore falls within the quantitative research paradigm.

3.6. Study population

The study population for the study included all participants with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders after they sustained a CVI and were admitted to the TRC for rehabilitation. Participants from various hospitals in Gauteng Province refer participants post-stroke to the TRC for rehabilitation.

3.7. Sample group

Eligibility criteria for participants in the trial are listed below.

3.7.1. Inclusion criteria

(1) Participants presenting with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders were recruited for the trial.

(2) Participants who had sustained a clinical ischaemic or hemorrhagic stroke (Blanton et al, 2006).

(3) Participants in the age group 19 – 74 (Robertson, McMillan, MacLeod, Edgeworth & Brock, 2002; Lennon et al, 2006).

(4) Willingness and cognitive ability of the participant to give written informed consent to participate in the trial.

Written informed consent included a thumb print made in front of witnesses in case of a participant who was unable to give a signature.

(5) Glasgow coma scale of at least 14 (Hafsteinsdóttir, 2005).

Cognition is an essential aspect in the re-education of motor and postural control. Cognitive processes such as attention, emotion and motivation relate to perception and the action (motor) systems. The degree of cognitive impairment of a stroke participant, therefore, determines their response to the

rehabilitation process and functional outcome post-stroke (Shumway-Cook & Woollacott, 2007).

(6) The ability to follow instructions (Lennon et al, 2006).

The ability to follow verbal and visual instructions is essential to intent and goal achievement during task-specific activities. The ability to follow instructions contributes to the participant's response to the rehabilitation process and therefore influences the functional outcome in a participant who has sustained a stroke (Shumway-Cook & Woollacott, 2007).

3.7.2. Exclusion criteria

Participants were excluded if they:

(1) Scored less than seven (<7) on the Mini-Mental State Examination (MMSE) (Hafsteinsdóttir, 2005) – Addendum 3.

Participants suffering from cortical dementia may react poorly to rehabilitation (Linden, Samuelsson, Skoog & Blomstrand, 2005) and were excluded from the study for this reason.

(2) Had a history of an organic disorder or major psychiatric problems likely to influence cerebral function (Blanton et al, 2006).

A cortical dysfunction prior to the stroke may negatively influence a participant's response to rehabilitation and such participants were excluded from the study for this reason (Robertson et al, 2002; Linden et al, 2005).

(3) Other co-morbid disease or disability such as cancer or amputation that would have prevented or limited the assessment of the participants and their participation or follow-up over a period of twenty (20) weeks (Robertson et al, 2002; Blanton et al, 2006; Lennon et al, 2006).

(4) Participation in other pharmacological or rehabilitation intervention studies that could have confounded the results of this study (Blanton et al, 2006).

(5) Participants' eligible for inclusion into the study but who planned to move from their residential areas within twenty (20) weeks after they had been admitted to the study was excluded from the trial (Blanton et al, 2006) because they would not have been able to participate in the follow-up intervention from week 8 to week 20 post discharge.

3.7.3. Sample size

Twenty-four (24) participants with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders after a CVI and who were admitted to the TRC were recruited to participate in the study from October 2009 to February 2011. The sample size of 24 participants was recruited based on the calculation to detect a 1 SD difference with (eighty) 80% power using ANCOVA.

Participants were divided into two groups of twelve (12) participants each: Group 1 = Experimental Group and Group 2 = Control Group.

- Group 1 (Experimental Group) received saccadic eye movement training with visual scanning exercises integrated with task-specific activities from Day 1 for four (4) consecutive weeks since their admission to the TRC.

- Group 2 (Control Group) received task-specific activities from Day 1 for four (4) consecutive weeks since their admission to the TRC.

3.7.4. Matching of the sample group

Participants who met the inclusion and exclusion criteria of the study (paragraph 3.7.1. and paragraph 3.7.2.) were screened based on their functional activity level as measured on the SAS by an independent assessor directly after they had been admitted to the TRC. The first participant who was eligible for participation in the study was allocated to Group 1. When a participant's SAS score matched a participant's score who was previously allocated to a specific group, that particular participant was placed in the opposite group from the existing matched participant. Participants who matched a previous participant's score on the SAS were automatically placed in the opposite group. If a participant had a score that did not match another participant's SAS score, the participant was randomly allocated to either Group1 or Group 2.

Participants were matched and allocated based on their scores on the SAS to ensure that participants in the two groups were comparable with regard to their level of functional activity. The allocation process was repeated until twelve (12) participants

had been allocated to each group. The participants from Group 1 and Group 2 were blinded to the group they were assigned to (Blanton et al, 2006). The two (2) groups of twelve (12) participants in each group did not make provision for drop-out of participants in the study. If participants dropped out of the study for any reason, another participant was recruited to replace him/her during the first four (4) weeks of the study.

3.8. Research process

After a participant was admitted to TRC the study was explained to the participants and informed consent was obtained from them. The participants were also informed that participation in the trial was voluntary and that they would not be coerced to participate. Each potential participant gave his/her written consent before he or she was admitted as a participant into the study (Addendum 4a).

After written consent was obtained from all participants and the allocation of the participants to Groups 1 and 2 was completed, the participants' demographical information was obtained (Addendum 4b) and their level of functional activity was assessed on the SAS. After the demographical information was obtained, participants in both groups were assessed in terms of their functional ability based on the framework of the International Classification of Functioning, Disability and Health (ICF) (Ustun et al, 2003). Within the International Classification of Functioning, Disability and Health (ICF) (Ustun et al, 2003) as the disability framework the participants' were assessed on the levels of body impairment and functional activity by using the selected clinical assessment tools and outcome measures. Outcome measures used in the study are displayed in Table 3.3. Assessment at baseline was

conducted immediately after the participants were allocated to Groups 1 and 2. Their baseline measurement on the selected outcome measures was administered before commencement of the intervention.

The intervention period commenced directly after the baseline assessment and continued for four (4) consecutive weeks, five (5) days per week. The period of intervention consisted of four (4) weeks because it is the average period of time participants spend in the TRC for post-stroke rehabilitation.

3.8.1. Intervention

During the intervention period of four (4) consecutive weeks, Group 1 (Experimental Group) received saccadic eye movement training with visual scanning exercises integrated with task-specific activities five (5) weekdays starting from Day 1 for four (4) consecutive weeks. Group 2 (Control Group) received task-specific activities five (5) weekdays starting from Day 1 for four (4) consecutive weeks.

3.8.2. The intervention participants in Group 1 and Group 2 received

Participants from Group 1 (Experimental Group) received saccadic eye movement training with visual scanning exercises integrated with task-specific activities. Only the guide of the principles of the interventions is discussed in this paragraph because the principles were adapted to each participant's functional ability. The flow of each therapy session is presented in Table 3.1.

Table 3.1. The flow of each therapy session of participants from Group 1 (Chan, Chan & Au, 2006)

Steps followed	Task-specific activities
Step 1	• Identification of the deficits and missing components during the performance of tasks. • Assign participant to appropriate steps that the participant need to be trained in to be able to perform the original task.
Step 2	• Select three (3) skills in each session that are specific to the deficits and missing components identified in Step 1 and that share similar performance components with the functional tasks trained in the same session.
Step 3	• Practice the skills and reinforce the practice of the missing components throughout the treatment session.
Step 4	• Transfer the skills practiced in Step 2 and Step 3 to practice of the functional tasks in accordance with the level of balance function of the participant.

The visual scanning exercises integrated with task-specific activities consisted of dual-task activities such as bridging in supine while performing saccadic eye movements on a HART-chart (Addendum 13) or flash cards (UNO play cards / regular playing cards). Dual task activities require the ability to allocate information-processing resources between two relevant tasks and to maintain sufficient attention on the intended task during the dual-task performance (Siu & Woollacott, 2007; Gorman, 2007). Guide of the principles of visual scanning exercises integrated with

task-specific activities and the principles of progression of these exercises are presented in Table 3.2.

Table 3.2. Guide of the principles of visual scanning exercises integrated with task-specific activities and the principles of progression of these exercises

FUNCTIONAL POSITIONS	VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY	PROGRESSION OF VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY
SUPINE **PROGRESSION:** Bridging with feet on a balance mat Bridging with feet on a balance ball	**BRIDGING:** Turn head towards impaired side. Bridge while doing saccadic eye movements by reading the individual letters or numbers aloud on a HART-chart or flash cards (UNO play cards / regular cards).	Lift buttocks up, read letter, drop buttocks read letter. Start reading on the left (L) of the HART – chart, read letters from (L) to right (R). Reading rows from top to bottom. Progress to larger saccadic eye movements and visual search strategies by reading the letter furthest on the (L) and be able to "jump" with their eyes immediately to the letter furthest on the (R). Repeat by reading the second letter on the (L) and immediately the second letter on the (R). Repeat till the middle of the row inwards. Start in the middle of the row and progress from (L) to (R). Increase the saccadic eye movements by progressing outwards towards the furthest letter/number on the (L) and (R).
SIDE LYING TO SITTING	Move from supine to side lying and from side lying to sitting while fixating the eyes on a card.	Incorporate smooth pursuit eye movements and visual fixation by tracking of an object: (1) Patient fixates on an object that is moving towards the impaired / affected side.

FUNCTIONAL POSITIONS	VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY	PROGRESSION OF VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY
		(2) Keep eyes fixated on object, head may turn. (3) <u>Progression</u>: Keep head still while continuing to fixate on an object that is moving towards the impaired / affected side.
SITTING **<u>PROGRESSION:</u>** Sitting on a balance mat Sitting on a roller Sitting on an exercise ball	Start reading on the left (L) of the HART – chart, read letters from (L) to right (R). Reading rows from top to bottom. Progress to larger saccadic eye movements and visual search strategies by reading the letter furthest on the (L) and be able to "jump" with their eyes immediately to the letter furthest on the (R). Repeat by reading the second letter on the (L) and immediately the second letter on the (R). Repeat till the middle of the row inwards. Start in the middle of the row and progress from (L) to (R). Increase the saccadic eye movements by progressing outwards towards the furthest letter/number on the (L) and (R).	<u>Progress functional position to:</u> (1) Sitting on a balance mat while performing visual scanning exercises. (2) Sitting on balance disc while performing visual scanning exercises. <u>Progress visual scanning exercises to</u>: Progress to larger saccadic eye movements and visual search strategies by using two (2) HART-charts side by side. Incorporate smooth pursuit eye movements and visual fixation by tracking of an object: (4) Patient fixates on an object that is moving towards the impaired / affected side. Keep eyes fixated on object, head may turn. (5) <u>Progression</u>: Keep head still while continuing to fixate on an object that is moving towards the impaired / affected side.

FUNCTIONAL POSITIONS	VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY	PROGRESSION OF VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY
SIT TO STAND **PROGRESSION:** With support in front of a table Without support of a table Sit to stand on an even surface Sit to stand on an uneven surface i.e. balance mat	Move from sitting to standing while fixating the eyes on a card.	Progress functional activity to: Move from sit to stand while reading a letter, followed by moving from standing to sitting while reading a letter/number. Start reading on the left (L) of the HART – chart, read letters from (L) to right (R). Reading rows from top to bottom. Progress to larger saccadic eye movements and visual search strategies by reading the letter furthest on the (L) and be able to "jump" with their eyes immediately to the letter furthest on the (R). Repeat by reading the second letter on the (L) and immediately the second letter on the (R). Repeat till the middle of the row inwards. Start in the middle of the row and progress from (L) to (R). Increase the saccadic eye movements by progressing outwards towards the furthest letter/number on the (L) and (R). Progress to larger saccadic eye movements and visual search strategies by using two (2) HART-charts one (1) above and one (1) below each other.
STANDING With support in front of a table Without support of a table	Perform saccadic eye movements with visual scanning exercises while in standing.	Progress functional position to: (1) Standing on a proprioception mat while performing visual scanning exercises. (2) Standing on balance disc/ball while performing visual scanning exercises.

FUNCTIONAL POSITIONS	VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY	PROGRESSION OF VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY
With an assistive device – walking frame; crutch; quadpod; tripod, walking stick Without an assistive device Standing near a wall for support Stand in the middle of a room without support		(3) Standing on a mini – trampoline while performing visual scanning exercises.
HALF- **STANDING** With support in front of a table Without support of a table With an assistive device – walking frame; crutch; quadpod; tripod, walking stick Without an assistive device Standing near a wall for support Stand in the middle of a room without support	Place one (1) leg on a step while performing saccadic eye movements with visual scanning exercises.	<u>Progress functional position to:</u> (1) Alternate legs on the step while while performing visual scanning exercises. One (1) leg on the floor and one (1) leg on a step. (2) Alternate legs on the step while performing visual scanning exercises. One (1) leg on the floor and one (1) leg on a balance mat / Boso ball. (3) Alternate legs on the step while performing visual scanning exercises. One (1) leg on the balance mat and one (1) leg on a step. (4) Alternate legs on the step while performing visual scanning exercises. One (1) leg on the balance mat and one (1) leg on a balance ball.

FUNCTIONAL POSITIONS	VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY	PROGRESSION OF VISUAL SCANNING EXERCISES INTEGRATED WITH TASK-SPECIFIC ACTIVITY
		Progress visual scanning exercises to: Place (L) foot on a step while reading a letter, alternate legs by placing (R) foot on a step while reading a letter/number. Repeat activity until all letters/numbers on the HART-chart are read.
GAIT **PROGRESSION:** With an assistive device – walking frame; crutch; quadpod; tripod, walking stick Without an assistive device While holding a tray	Walking on an even surface while performing saccadic eye movements with visual scanning exercises on either a HART-chart or flash cards during gait.	Progress functional position to: (1) Walking with one (1) foot on an AIREX balance beam and the other foot on the floor (even surface) while performing saccadic eye movements with visual scanning exercises. (2) Walking in a figure of eight (8). Keep eyes fixated on a card on either the (L) or the (R) wall, while turning. Alternate card on (L) and (R) wall. (3) Walking on uneven surfaces while performing saccadic eye movements with visual scanning exercises on either a HART-chart or flash cards during gait. (4) Walking while holding a tray, placing cards on the tray while walking, reading the numbers on the cards aloud.

Participants from Group 2 (Control Group) received task-specific activities five (5) weekdays starting from Day 1 for four (4) consecutive weeks. The flow of each therapy session of Group 2 is presented in Table 3.1.

To monitor the participants' progress during the intervention, consecutive in-hospital assessments on the outcome measures were repeated once a week on a Friday during the intervention period of four (4) weeks.

In-hospital weekly assessments were performed as follows:

↓ ↓ ↓ ↓ ↓

Day 1----------Day 8----------Day 15----------Day 22----------Day 28

3.9. Control of bias in the research process

A qualified physiotherapist from the principal investigator's practice treated participants in Group 1 (experimental group) and one (1) physiotherapist from the TRC treated participants in Group 2 (control group). The principal investigator orientated and trained the two (2) physiotherapists in the task-specific treatment approach to rehabilitation of participants who had sustained a stroke and who suffered from unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke, to ensure that there was no difference in the application of the task-specific treatment approach to participants post-stroke between the two (2) physiotherapists.

Orientation and in-service training of the two (2) physiotherapists took place prior to the commencement of the trial. The participants in Group 1 and 2 were treated in

separate venues to control blinding of the participants throughout the study. The two (2) physiotherapists who treated the participants in Group 1 and Group 2 based their treatment on a client-centered approach to rehabilitation. The client-centered approach to rehabilitation entails the facilitation of active participation and responsibility of the participants and their caregivers in the rehabilitation process (Hammell, 2004).

An independent assessor (also a qualified physiotherapist) with sufficient experience in administration of the outcome measures used during the trial conducted the assessment of the participants on Day 1, Day 8, Day 15, Day 22 and Day 28, as well as week eight (8), week twelve (12), week sixteen (16) and week twenty (20) after the participants were discharged from TRC. All participants were assessed on the same day of the week. The independent assessor and participants in the clinical trial were blinded to the groups the participants were assigned to (Blanton et al, 2006).

Because rehabilitation is a multidisciplinary team approach, the participants in the clinical trial's treatment by other members of the rehabilitation team (namely, the occupational therapist, speech-and-language therapist and social worker) continued as usual at the TRC.

The average duration of physiotherapy sessions was approximately forty-five (45) minutes. Time spent on report writing, advice given to participants, family or caregivers and discussions with other members of the multi-disciplinary team were not included in the forty-five (45) minutes. Informal therapy that consisted of the implementation of acquired movement skills into tasks of daily living was regarded as

part of the 'home' / 'ward' exercise programme performed in addition to the formal therapy setting.

In order to determine whether there was a difference in the quality of life of participants in the experimental group (Group 1) and the control group (Group 2) as well as their ability to re-integrate into their communities, participants were followed up on a monthly basis and re-assessed at week eight (8), twelve (12), sixteen (16) and week twenty (20) after their rehabilitation (participation in the study) started on the Stroke Impact Scale Version 3.0 (SIS) and the walking ability questionnaire.

3.10. Reliability and validity of the clinical trial

In order to ensure reliability of the research data, a skilled assessor who was blinded to the groups that the participants were assigned to conduct all the assessments of the participants in the trial. All outcome measures that were used are internationally recognised and validated (refer to paragraph 2.7. and paragraph 2.8.). This ensured the reliability of the data captured and the data obtained. The results of this study may therefore be compared to those of similar studies where the same data capture methods or outcome measures were implemented nationally and internationally. The use of multiple outcomes measures could have resulted in a learning effect specifically the Mini-Mental State Examination and the SAS.

3.11. Assessment instruments

In this study the ICF (Ustun et al, 2003) was used as the model of disablement within which participants were assessed and treated. The outcome measures used in the

assessment of the effects of treatment on body impairment, functional activity and participation level are discussed in paragraph 2.7.

3.11.1. Body impairment level

The outcome measure used to assess the effects of treatment on body impairment level and the validity of the measures used are described in detail in paragraph 2.7. Assessments of impairment level were done using the following selected outcome measures:

(1) King-Devick Test © (Zoltan, 1996) (Addendum 5) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **oculomotor function**.

(2) Star Cancellation Test (Addendum 8) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **perceptual processing**.

(3) The Mini-Mental State Examination (MMSE) (Addendum 3) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group

2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **cognitive function**.

(4) The Hospital Anxiety and Depression Scale (HADS) (Addendum 11) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **level of anxiety and depression**.

3.11.2. Functional activity level

The outcome measure used to assess the effects of treatment on functional activity level and the validity of the measures used are described in detail in paragraph 2.7. and paragraph 2.8. Assessments on functional activity level were done using the following selected outcome measures:

(1) Stroke Activity Scale (Addendum 12) was selected to match and allocate participants in the study to the control and experimental groups prior to the study based on their functional activity level (as measured on the SAS) to ensure that participants in the two groups were comparable with regard to their functional activity level. The SAS was further selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with

unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **functional ability**.

(2) Barthel Index (Addendum 6) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **functional ability**.

(3) The Timed Up and Go Test (TUG) (Addendum 7) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **functional ability**.

3.11.3. Participation level

The outcome measure used to assess the effects of treatment on participation level and the validity of the measures used are described in detail in paragraph 2.10.1.3. Assessments on participation level were done using the following selected outcome measures:

(1) Stroke Impact Scale Version 3.0 (SIS) (Addendum 9) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with

unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **quality of life**.

(2) The walking ability questionnaire (Addendum 10) was selected to assess the effect of visual scanning exercises integrated with task-specific activities received by participants from Group 1 versus participants from Group 2 that received task-specific activities alone on participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders post-stroke's **quality of life**.

3.11.4. Summary of assessments completed during the trial

Summary of weekly in-hospital assessments and post-discharge assessments completed during the trial are indicated in Table 3.3.

Table 3.3. Summary of assessments completed during the trial

Outcomes measure	Day 1	Day 8	Day 15	Day 22	Day 28	Week 8	Week 12	Week 16	Week 20
Mini-Mental State Examination (MMSE)	X	X	X	X	X	X	X	X	X
King-Devick Test ©	X	X	X	X	X	X	X	X	X
Star Cancellation Test	X	X	X	X	X	X	X	X	X
The Hospital Anxiety and Depression Scale	X	X	X	X	X	X	X	X	X
Stroke Activity Scale (SAS)	X	X	X	X	X	X	X	X	X
Barthel Index (BI)	X	X	X	X	X	X	X	X	X

Timed Up and Go Test (TUG)	X	X	X	X	X	X	X	X	X
Stroke Impact Scale Version 3.0 (SIS)						X	X	X	X
The walking ability questionnaire						X	X	X	X

Post-discharge assessments were conducted at TRC out-patient facility. Participants were required to travel to and from TRC for the follow-up assessments at week eight (8), week twelve (12), week sixteen (16) and week twenty (20) post initiation of the clinical trial.

3.12. Retention of participants until study completion – attempting to minimise subjects lost to follow-up (Blanton, et al, 2006)

The researcher provided remuneration to cover transportation costs for participants to enable them to attend the follow-up assessments. Reimbursement of costs of travelling was based upon the residential area and individual participant's needs that were identified on completion of the demographical information sheet at baseline and subjective information provided by the participant prior to discharge from the TRC (Blanton et al, 2006).

Two (2) weeks prior to each scheduled re-assessment appointment the researcher made a telephone call to all the participants in the trial to remind them of their scheduled follow-up assessment date and time. Another telephone phone call was made one (1) week prior to the scheduled follow-up assessment to remind the

participant of the scheduled appointment. Regular phone calls were made to maintain communication with the subjects after discharge from the TRC and to minimise subjects lost to follow-up during the study (Blanton et al, 2006).

3.13. Pilot study

A pilot study was performed prior to commencement of the trial. The main aim of the pilot study was to test the research procedure and techniques of data gathering. Three (3) participants, who met the inclusion and exclusion criteria, participated in the pilot study. Two (2) participants were allocated to Group 1 (experimental group (n = 2)) and one (1) participant to Group 2 (control group (n = 1)). The participants were treated by the two (2) physiotherapists who treated the participants in Group 1 and Group 2. The independent assessor conducted the assessment of the participants on Day 1, Day 8, Day 15, Day 22 and Day 28 post-admission to TRC as well as week eight (8), week twelve (12), week sixteen (16) and week twenty (20) post discharge from the TRC. The assessor was blind to the participants assigned to the two (2) groups. Assessments were done by using the previously described outcome measures, with the exception of the Hospital Anxiety and Depression Scale (HADS) as described in paragraph 2.7.5.

Two (n = 2) participants showed improvement on the Mini-Mental State Examination, King-Devick Test ©, Star cancellation test, SAS, Barthel Index, Timed-up and Go Test, Stroke Impact Scale and Walking ability questionnaire from baseline to week twenty (20). One (n = 1) participant demonstrated illogical progress in performance on the Mini-Mental State Examination, Star Cancellation Test, Barthel Index, TUG Test during the period of intervention from baseline to week four (4). A careful

analysis of the results and investigation into the participant's daily routine following the illogical sequence of the results indicated that the participant's performance was in retrospect related to her emotional status. The participant presented with a state of anxiety and depression that seemed to have influenced her participation in therapy and influenced the participant's performance on the functional outcomes.

The HADS was, therefore, included as an outcome measure in the clinical trial and was implemented on a weekly basis (refer to Table 3.4). The HADS is a valid and reliable tool for the identification and quantification of depression and anxiety post-stroke, as described in paragraph 2.7.5.

No other changes were made to the research procedure.

3.14. Data analysis

For descriptive purposes it was assumed that given the small number of participants in each group, all data were non-normally distributed. Results were thus described with medians and 25th and 75th percentiles. For comparisons Mann Whitney U tests were done without adjustment for multiple comparisons. For comparing outcomes at week four (4), adjusting for baseline values, as well as the fact that subjects were matched a mixed model rank ANCOVA analysis was used where the week four (4) and baselines values were ranked and the ranked values used in the regression analyses. P values <=0.05 were regarded as statistically significant. All analyses were done in R 2.14.2.

3.15. Summary

In summary, Chapter 3 describes the study design and research methodology used in the clinical trial. All the participants who were included in the clinical trial underwent a four-week inpatient rehabilitation period at TRC. The rehabilitation (intervention) was based on the task-specific approach to rehabilitation that consisted of activities or components of activities that participants had to re-learn to perform in order to optimise their functional ability.

All participants received task-specific activities for the intervention period of four (4) consecutive weeks. The participants in Group 1 received saccadic eye movement training with visual scanning exercises integrated with their task-specific activities as part of the treatment as an “add on” intervention in this trial. In order to assess the participants’ quality of life and re-integration into their communities, participants were followed up on a monthly basis and re-assessed at week eight (8), twelve (12), sixteen (16) and week twenty (20) after their rehabilitation (participation in the study) commenced.

A detailed account of the analysis of the data and the discussion of the results gathered during the period of intervention of four (4) consecutive weeks of the double blind matched clinical trial is presented in Chapter 4. The demographic data of all the participants who participated in this clinical trial and the results of the outcome measures obtained at the pre-determined times are identified and described in the following chapter. Results gathered at week eight (8), week twelve (12), week sixteen (16) and week twenty (20) are presented in Addendum 14 because a large number of

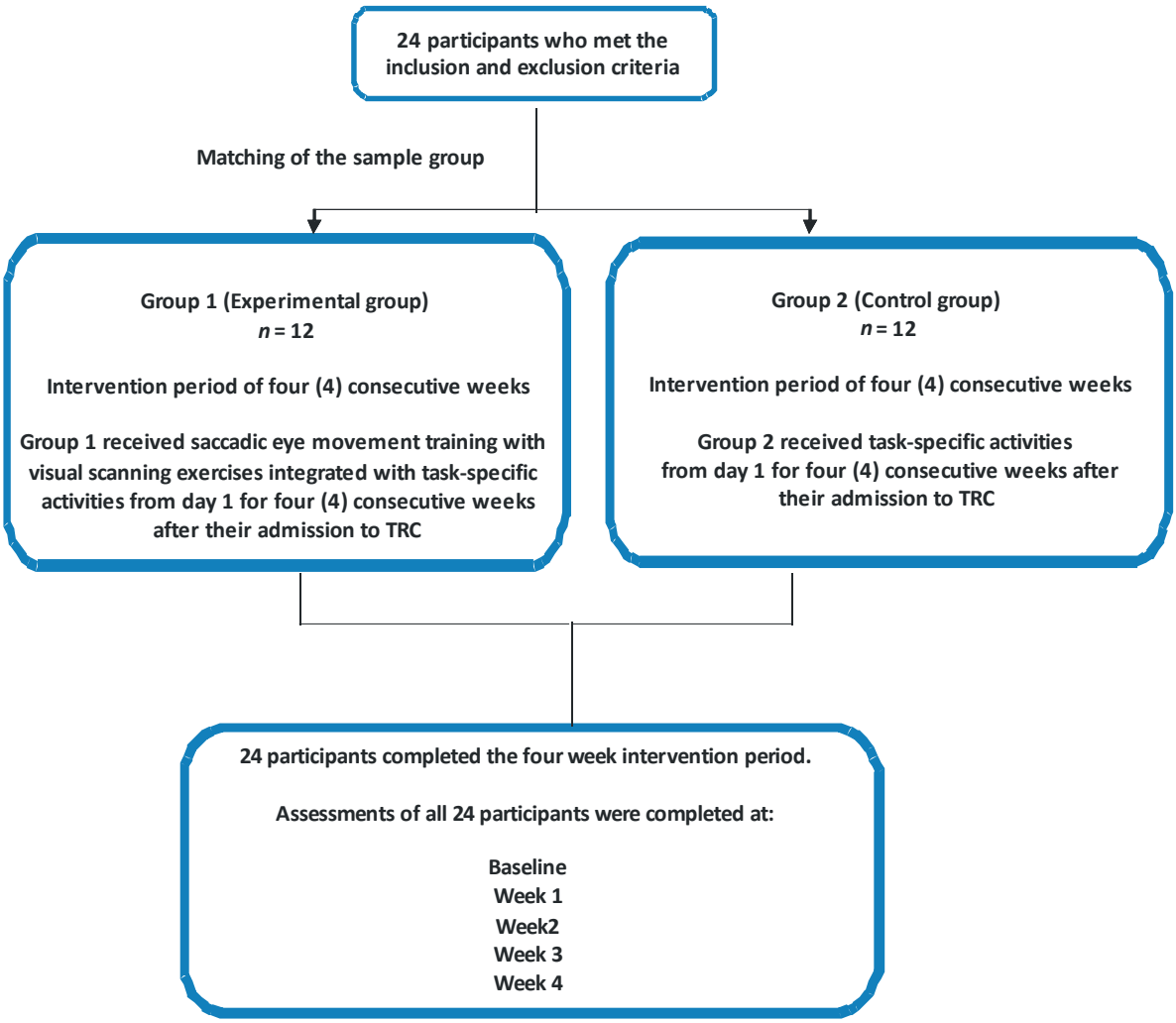
participants were lost to follow-up following discharge from the TRC after the first four (4) weeks (intervention period) of the study. The results and findings gathered at week eight (8), week twelve (12), week sixteen (16) and week twenty (20) after admission to the rehabilitation facility are therefore incomplete but are presented in Addendum 14.

CHAPTER 4

RESULTS OF THE STUDY

4.1. Introduction

A detailed account of the analysis of the data and a discussion of the results gathered during the period of intervention of four (4) consecutive weeks of the matched-pair randomised controlled trial are presented visually by means of tables in Chapter 4. The discussion of the results gathered during this matched-pair randomised controlled trial will be presented based on the aims and the objectives stated in Chapter 1 (paragraphs 1.7 & 1.8). The course of the study is displayed in Figure 4.1.



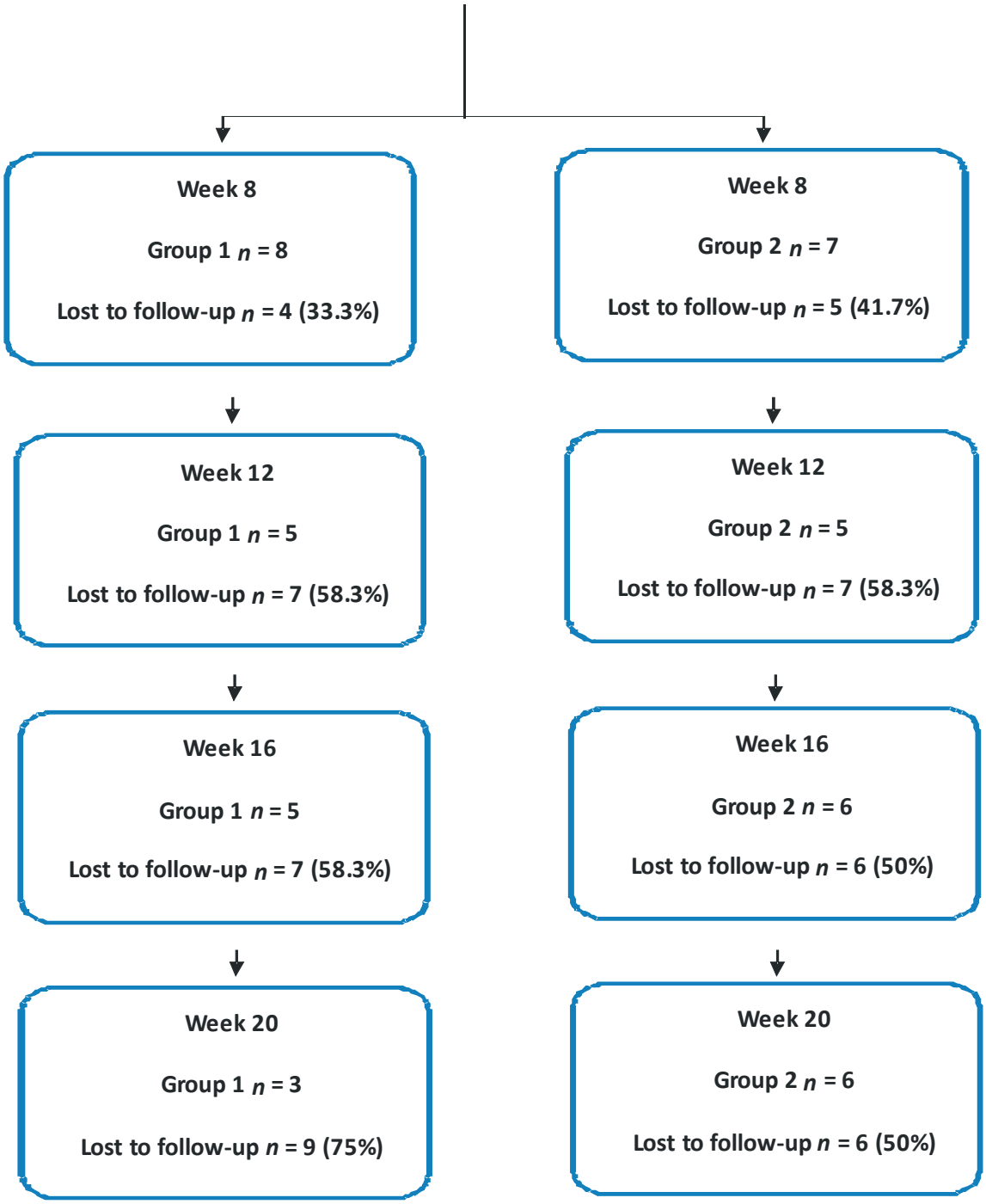


Figure 4.1. The course of the study

4.2. Demographical data of the participants in the clinical trial

The demographical data of participants from Group 1 and Group 2 is displayed in Table 4.1.

Table 4.1. The demographic data of participants from Group 1 and Group 2

DEMOGRAPHIC DATA – Participant characteristics Group 1: *n* = 12 Group 2: *n* = 12	***P* – value** P values < = 0.05 (statistically significant)
AGE	p = 0.315
GENDER	p = 1
RACE	p = 0.68
AFFECTED SIDE POST-STROKE	p = 1
DOMINANT SIDE PRIOR TO THE STROKE	p = 1
FUNCTIONAL ABILITY ON THE SAS BEFORE THE TRIAL	p = 0.24
RESIDENTIAL AREAS	p = 0.37
ACCESS TO ELECTRICITY IN RESIDENCE	p = 1
ACCESS TO RUNNING WATER IN RESIDENCE	p = 0.64
DISTANCE TO RUNNING WATER NEAR RESIDENCE	p = 0.42
ACCESS TO A TOILET IN RESIDENCE	p = 1
WALKING DISTANCE TO TOILET NEAR RESIDENCE	p = 0.92
ACCESS TO TRANSPORT	p = 1
WALKING DISTANCE TO PUBLIC TRANSPORT	p = 0.55
ACCESS TO A HEALTH CARE SETTING	p = 1
TRAVELLING DISTANCE TO A HEALTH CARE SETTING	p = 0.08
ACCESS TO A CARE GIVER AFTER DISCHARGE FROM THE REHABILITATION FACILITY	p = 0.48

DEMOGRAPHIC DATA – Participant characteristics Group 1: *n* = 12 Group 2: *n* = 12	***P* – value** P values < = 0.05 (statistically significant)
LEVEL OF SCHOOLING	p = 0.68
EMPLOYMENT STATUS AT THE TIME OF THE STROKE	p = 0.679
TYPE OF WORK	p = 0.301

No statistical difference in the demographic data between the groups was found at baseline. Based on the results in Table 4.1 it can be concluded that the two groups were comparable with each other regarding age, gender, race, affected side post-stroke and dominant side prior to the stroke at the beginning of the study. These factors were therefore not expected to have any influence on the outcome of the intervention(s) on the dependent variables.

No statistical difference between the demographic data regarding the residential areas, access to basic services and level of education between the groups was found at baseline. Based on the interpretation, it can be concluded that the two groups were comparable with each other regarding home environment, socio-economic status and level of education at the beginning of the study and the demographic data was therefore not expected to have any influence on the outcome of the intervention(s) on the dependent variables.

4.2.1. Matching based on functional activity level

Participants in the study were matched and allocated to the control and experimental groups prior to the study based on their functional activity level as measured on the SAS to ensure that participants in the two groups were comparable with regard to their functional activity level. The SAS score at baseline was fairly similar between Group 1 and Group 2 before the study commenced. No statistical difference was noted between the groups at baseline ($p = 0.24$). Based on the interpretation of the SAS, the motor function of participants from Group 1 and Group 2 was similar at the beginning of the intervention period (baseline).

It can be concluded that the two groups were comparable with each other regarding their functional activity level, specifically their motor function at the beginning of the study. Participants' functional activity level, specifically their residual motor function prior to the intervention, was therefore not expected to have any influence on the outcome of the intervention(s) on the dependent variables.

4.3. Results from outcome measures over the four-week intervention period

4.3.1. Results of the assessment of participants' oculomotor function

4.3.1.1. The King-Devick Test ©

(1) Time taken to complete the King-Devick Test © over the four-week intervention period

Results of the King-Devick Test © over the four-week intervention period are displayed in Table 4.2.

Table 4.2. Results of the time taken to complete the King-Devick Test © over the four-week intervention period for Group 1 and Group 2

King-Devick Subtest 1	[ALL]	Group 1	Group 2	
	(Time) n=24	(Time) n=12	(Time) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	53.5 [32.8; 65.5]	53.5 [32.8; 68.9]	53.5 [39.6; 60.0]	0.82
Week 1	43.3 [30.4; 57.4]	52.1 [30.4; 59.9]	32.3 [30.6; 48.4]	0.30
Week 2	39.9 [34.4; 57.4]	41.7 [36.2; 58.5]	37.5 [34.4; 50.7]	0.73
Week 3	32.7 [27.6; 43.4]	34.1 [26.9; 58.3]	32.7 [28.3; 37.6]	0.82
Week 4	32.3 [28.7; 40.1]	34.8 [28.8; 50.4]	31.3 [28.6; 35.9]	0.56
King-Devick Subtest 2	[ALL]	Group 1	Group 2	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	70.8 (75.9)	61.5 (17.8)	80.1 (107.4)	0.57
Week 1	52.4 (35.4)	57.1 (25.6)	47.6 (43.7)	0.52
Week 2	57.5 (36.7)	60.7 (41.4)	54.3 (32.8)	0.68
Week 3	49.0 (27.4)	54.9 (35.9)	43.1 (14.2)	0.31
Week 4	46.1 (26.2)	49.0 (31.2)	43.2 (21.2)	0.60
King-Devick Subtest 3	[ALL]	Group 1	Group 2	
	(Time) n=24	(Time) n=12	(Time) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	71.4 [46.7; 106.9]	55.5 [42.6; 79.9]	92.0 [63.3; 115.0]	0.15
Week 1	55.8 [36.8; 71.7]	59.1 [47.8; 84.4]	48.9 [31.7; 61.8]	0.36
Week 2	44.6 [35.8; 68.2]	47.9 [35.8; 68.4]	43.2 [35.2; 66.3]	0.95
Week 3	43.8 [36.4; 67.9]	49.5 [36.1; 74.1]	42.4 [36.9; 55.7]	0.64
Week 4	41.6 [34.0; 68.6]	41.6 [37.4; 79.5]	43.3 [32.9; 61.1]	0.82

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.2. For comparisons between groups at weekly assessments, Mann Whitney U tests were done without adjustment for multiple comparisons. No statistical difference was noted on the King-Devick Subtest 1 ($p = 0.82$), King-Devick Subtest 2 ($p = 0.57$) and King-Devick Subtest 3 ($p = 0.15$) at baseline between Group 1 and Group 2. The implications of the King-Devick Subtest 1, King-Devick Subtest 2 and King-Devick Subtest 3 scores at baseline are that the residual oculomotor function in participants from Group 1 and Group 2 was similar at the beginning of the study. Based upon the interpretation of the King-Devick Subtest 1, 2 and 3 scores, participants in both groups suffered from poor oculomotor function and impairment of the visual efficiency processes, specifically slow saccadic eye movements, at the beginning of the study.

Impairment of the oculomotor function and visual efficiency processes specifically slow saccadic eye movements, in participants from Group 1 and Group 2 improved over the four-week intervention period. For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing ranks of both groups after the four-week intervention period adjusting for matching and baseline values, the King-Devick Subtest 1 ($p= 0.45$) and King-Devick Subtest 2 ($p= 0.76$) scores at week four (4) was not significantly different for the two groups.

Comparing ranks of both groups after the four-week intervention period and adjusting for matching and baseline values, the King-Devick Subtest 3 score at week four (4) was statistically significantly better in participants from Group 1 compared to those from Group 2 (p= 0.02). The oculomotor strategies and visual efficiency processes, specifically the saccadic eye movements, required to complete the King-Devick Subtest 3 were significantly better in participants from Group 1 compared to those from Group 2 (p= 0.0211). The implication is that participants from Group 1 presented with better oculomotor function, visual efficiency processes and saccadic eye movements compared to participants from Group 2 post-intervention. The King-Devick Subtest 3 is the most advanced subtest of the King-Devick Test © in the sense that the King-Devick Subtest 3 requires larger saccadic eye movements and visual search strategies than King-Devick Subtest 1 and King-Devick Subtest 2. It is interesting to note that the difference in the two groups only presented in the more difficult test which displays a higher level of oculomotor function, visual efficiency processes and saccadic eye movements and not in the easier King Devick Subtest 1 and King Devick Subtest 2.

(2) Average errors during completion of the King-Devick Test © over the four (4) – week intervention period

Results of the average number of errors made during the completion of the King-Devick Test © over the four-week intervention period are displayed in Table 4.3.

Table 4.3. The average number of errors made during the completion of the King-Devick Test © over the four-week intervention period

Average errors - King-Devick Subtest 1	[ALL]	Group 1	Group 2	
	(Average errors) n=24	(Average errors) n=12	(Average errors) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	<0.1 [0.0; 0.2]	0.1 [<0.1; 0.2]	0.0 [0.0; 0.3]	0.21
Week 1	<0.1 [0.0; 0.1]	<0.1 [0.0; 0.2]	<0.1 [0.0; <0.1]	0.39
Week 2	<0.1 [0.0; 0.1]	<0.1 [0.0; 0.2]	<0.1 [0.0; 0.1]	0.81
Week 3	0.0 [0.0; 0.1]	<0.1 [0.0; 0.1]	0.0 [0.0; 0.1]	0.73
Week 4	0.0 [0.0; <0.1]	<0.1 [0.0; 0.1]	0.0 [0.0; <0.1]	0.17
Average errors - King-Devick Subtest 2	[ALL]	Group 1	Group 2	
	(Average errors) n=24	(Average errors) n=12	(Average errors) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	<0.1 [0.0; 0.2]	<0.1 [0.0; 0.1]	0.0 [0.0; 0.2]	0.88
Week 1	<0.1 [0.0; 0.1]	<0.1 [0.0; 0.2]	<0.1 [0.0; 0.1]	0.57
Week 2	<0.1 [0.0; 0.2]	0.1 [0.0; 0.3]	<0.1 [0.0; 0.1]	0.20
Week 3	0.0 [0.0; 0.2]	<0.1 [0.0; 0.1]	0.0 [0.0; 0.2]	0.38
Week 4	<0.1[0.0; 0.1]	<0.1 [0.0; 0.2]	<0.1 [0.0; 0.1]	0.70
Average errors - King-Devick Subtest 3	[ALL]	Group 1	Group 2	
	(Average errors) n=24	(Average errors) n=12	(Average errors) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	0.2 [<0.1; 0.4]	0.1 [<0.1; 0.5]	0.2 [0.1; 0.3]	0.45
Week 1	0.2 [0.1; 0.3]	0.3 [0.1; 0.6]	0.2 [0.1; 0.2]	0.49
Week 2	0.2 [<0.1; 0.3]	0.2 [<0.1; 0.5]	0.2 [<0.1; 0.2]	0.49
Week 3	0.2 [0.1; 0.3]	0.2 [<0.1; 0.4]	0.2 [0.1; 0.2]	0.95
Week 4	0.1 [<0.1; 0.3]	0.2 [0.0; 0.4]	0.1 [0.1; 0.2]	0.73

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.3. For comparisons between groups at weekly assessments, Mann Whitney U tests were completed without adjustment for multiple comparisons. The average number of errors made during the completion of the King-Devick Subtest 1 ($p = 0.21$), King-Devick Subtest 2 ($p = 0.88$) and King-Devick Subtest 3 ($p = 0.45$) at baseline by participants from Group 1 and Group 2 were not significantly different. The implications of the average number of errors made at baseline are that the accuracy with which the participants from Group 1 and Group 2 completed the King-Devick Subtest 1, King-Devick Subtest 2 and King-Devick Subtest 3 was similar at the beginning of the study.

No statistical difference was noted in the average number of errors made during the completion of the King-Devick Subtest 1 ($p = 0.17$), King-Devick Subtest 2 ($p = 0.70$) and King-Devick Subtest 3 ($p = 0.73$) by participants from Group 1 and Group 2 after the four-week intervention period.

4.3.2. Results of the assessment of participants' functional ability

4.3.2.1. The Stroke Activity Scale

Results of the Stroke Activity Scale of participants from Group 1 and Group 2 over the four-week intervention period are displayed in Table 4.4.

Table 4.4. Results of the Stroke Activity Scale of participants from Group 1 and Group 2 over the four-week intervention period

Stroke Activity Scale	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	10.0 [7.8; 13.0]	10.5 [9.0; 13.2]	8.5 [6.8; 12.2]	0.24
Week 1	8.0 [5.8; 10.0]	8.5 [6.8; 10.0]	7.5 [5.0; 9.8]	0.52
Week 2	11.0 [8.0; 14.0]	12.0 [10.2; 14.2]	9.0 [7.8; 12.5]	0.12
Week 3	11.0 [9.8; 14.0]	11.5 [11.0; 14.5]	10.0 [7.8; 12.5]	0.09
Week 4	12.0 [9.8; 14.2]	13.0 [11.0; 15.2]	10.5 [9.0; 13.2]	0.09

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.4. For comparisons between groups at weekly assessments, Mann Whitney U tests were completed without adjustment for multiple comparisons. The SAS score at baseline was fairly similar between Group 1 and Group 2 before the study commenced. No statistical difference was noted between the groups at baseline ($p = 0.24$). Based on the interpretation of the SAS, the motor function of participants from Group 1 and Group 2 was similar at the beginning of the intervention period (baseline).

The SAS score of participants in both groups improved over the four-week intervention period. Participants from Group 1 and Group 2's motor function improved over the four-week intervention period. No statistical difference was noted on the SAS between Group 1 and Group 2 after the intervention period of four (4) weeks ($p = 0.09$). For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on

ranks adjusted for matching and baseline values was also not statistically significant (p = 0.09) between Group 1 and Group 2 after the four-week intervention period. The motor function of participants from both groups was fairly similar after the four-week intervention period as measured on the SAS.

4.3.2.2. The Barthel Index

Results of the Barthel Index (BI) of participants from Group 1 and Group 2 over the four-week intervention period are displayed in Table 4.5.

Table 4.5. Results of the Barthel Index of participants from Group 1 and Group 2 over the four-week intervention period

Barthel Index	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	45.0 [33.8; 53.8]	40.0 [28.8; 50.0]	45.0 [35.0; 53.8]	0.54
Week 1	55.0 [40.0; 80.0]	57.5 [48.8; 81.2]	45.0 [35.0; 65.0]	0.20
Week 2	60.0 [48.8; 90.0]	62.5 [58.8; 95.0]	47.5 [35.0; 71.2]	0.02
Week 3	70.0 [53.8; 95.0]	77.5 [60.0; 96.2]	57.5 [43.8; 78.8]	0.07
Week 4	85.0 [55.0; 100.0]	90.0 [72.5; 100.0]	55.0 [45.0; 95.0]	0.04

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.5. For comparisons between groups at weekly assessments, Mann Whitney U tests were done without adjustment for multiple comparisons. The BI score at baseline was fairly similar between Group 1 and Group 2. No statistical difference was found between the groups at baseline (p = 0.54). Based on the interpretation, the BI score at

baseline of participants in Group 1 and Group 2 was an indication of severe dependence in the performance of ADL at the beginning of the intervention period. Prior to the intervention, the levels of dependence in participants from Group 1 and Group 2 were fairly equal.

The BI score of participants in Group 1 increased to a large extent over the four-week intervention period indicating that the level of dependence of participants in Group 1 decreased over the four-week intervention period. Participants from Group 1's level of functional performance in ADL improved over the intervention period. Based on the interpretation of the BI, participants from Group 1 presented with a "moderate" level of dependence post-intervention.

The BI score of participants in Group 2 increased minimally over the four-week intervention period. The interpretation of the BI post-intervention implies that participants from Group 2 continued to present with a severe dependence in the performance of ADL. A statistically significant difference ($p = 0.04$) was noted when comparing the functional improvement between the two groups after the intervention period. For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks adjusted for matching and baseline values was also statistically significant ($p = 0.004$) between Group 1 and Group 2 after the four-week intervention period. Participants from Group 1 presented with a higher level of functional performance in ADL compared to participants from Group 2 after the intervention period.

4.3.2.3. The Timed Up and Go Test

Results of the Timed Up and Go Test (TUG) of participants from Group 1 and Group 2 over the four-week intervention period are displayed in Table 4.6.

Table 4.6. Results of the TUG of participants in Group 1 and Group 2 over the four-week intervention period

Timed Up and Go Test (TUG)	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	0.1 [0.0; 0.1]	0.1 [0.1; 0.1]	0.0 [0.0; 0.1]	0.19
Week 1	0.1 [0.1; 0.4]	0.2 [0.1; 0.4]	0.1 [0.1; 0.2]	0.17
Week 2	0.1 [0.1; 0.2]	0.1 [0.1; 0.2]	0.1 [<0.1; 0.1]	0.40
Week 3	0.1 [0.1; 0.3]	0.1 [0.1; 0.3]	0.1 [<0.1; 0.2]	0.36
Week 4	0.1 [0.1; 0.4]	0.1 [0.1; 0.4]	0.1 [<0.1; 0.2]	0.23

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.6. For comparisons between groups at weekly assessments, Mann Whitney U tests were done without adjustment for multiple comparisons. The TUG score at baseline was fairly even between Group 1 and Group 2. No statistical difference was noted between the groups at baseline (p = 0.19). Prior to the intervention, the locomotor performance and the ability to perform sequential motor tasks relative to walking and turning in participants from Group 1 and Group 2 were fairly similar.

The TUG score of participants in both groups improved over the four-week intervention period. Participants from Group 1 and Group 2's locomotor performance and the ability to perform sequential motor tasks relative to walking and turning improved over the four-week intervention period. No statistical difference was noted on the TUG between Group 1 and Group 2 after the intervention period of four (4) weeks ($p = 0.23$). For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks adjusted for matching and baseline values was also not statistically significant ($p = 0.56$) between Group 1 and Group 2 after the four-week intervention period.

4.3.3. Results of the assessment of participants' perceptual processing and cognitive function

4.3.3.1. The Star Cancellation Test

(1) Number of stars cancelled during the completion of the Star Cancellation Test over the four-week intervention period

Results of the number of stars "cancelled" during the completion of the Star Cancellation Test over the four-week intervention period are displayed in Table 4.7.

Table 4.7. Results of the number of stars "cancelled" during the completion of the Star Cancellation Test over the four-week intervention period

Star Cancellation Test	[ALL]	Group 1	Group 2	
	(Number of stars) n=24	(Number of stars) n=12	(Number of stars) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	39.0[24.2; 51.2]	26.0 [19.5; 44.8]	45.0 [36.8; 53.0]	0.06
Week 1	40.5 [30.5; 50.2]	44.0 [30.5; 51.2]	39.0 [31.2; 44.0]	0.54
Week 2	48.5 [32.5; 53.0]	50.0 [41.0; 53.0]	46.5 [32.5; 51.5]	0.45
Week 3	44.0 [41.0; 52.2]	49.5 [43.0; 53.2]	42.5 [38.0; 52.0]	0.15
Week 4	45.0 [35.5; 53.0]	50.5 [43.0; 53.0]	41.0 [33.5; 47.8]	0.17

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.7. For comparisons between groups at weekly assessments, Mann Whitney U tests were done without adjustment for multiple comparisons. Near statistical difference was noted on the Star Cancellation Test at baseline between Group 1 and Group 2 ($p = 0.06$). The implications of the Star Cancellation score at baseline are that the level of USN in the near extrapersonal space observed in both groups was fairly similar at the beginning of the study, prior to the intervention.

The number of “cancelled” stars by participants in Group 1 increased over the intervention period of four (4) weeks. Based on the interpretation of the Star Cancellation Test, the USN in the near extrapersonal noted in participants from Group 1 improved over the four-week intervention period. For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4)

and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks of stars "cancelled" after adjusting for matching and baseline values was statistically significant (p = 0.02) between Group 1 and Group 2. The number of "cancelled" stars by participants from Group 2 decreased over the intervention period of four (4) weeks. Based on the interpretation of the Star Cancellation Test, the USN noted in participants from Group 2 at baseline increased over the four-week intervention period.

(2) The time taken to complete the Star Cancellation Test over the four (4) – week intervention period

Results of the time taken to complete the Star Cancellation Test over the four-week intervention period are indicated in Table 4.8.

Table 4.8. Results of the time taken to complete the Star Cancellation Test over the four-week intervention period

Time taken to complete the Star Cancellation Test	[ALL]	Group 1	Group 2	
	(Time) n=24	(Time) n=12	(Time) n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	124.7 [108.6; 166.7]	119.8 [108.6; 142.5]	131.0 [106.0; 175.9]	0.77
Week 1	118.5 [70.1; 196.7]	129.8 [69.4; 196.7]	116.1 [73.7; 167.9]	0.69
Week 2	108.2 [66.9; 181.8]	108.2 [56.0; 146.2]	105.8 [71.1; 216.9]	0.49
Week 3	110.6 [77.1; 164.0]	123.0 [78.2; 164.0]	102.5 [77.1; 156.2]	1.00
Week 4	86.9 [71.7; 165.9]	91.1 [74.6; 176.3]	86.9 [70.9; 127.2]	0.73

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.8. For comparisons between groups at weekly assessments, Mann Whitney U tests were completed without adjustment for multiple comparisons. No statistical difference was noted in the time taken to complete the Star Cancellation Test at baseline between Group 1 and Group 2 ($p = 0.77$). The implications of the Star Cancellation score at baseline imply that the speed with which the Star cancellation Test is completed by both groups was similar at the beginning of the study.

The speed with which both groups completed the Star Cancellation Test improved over the four-week intervention period. For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks adjusted for matching and baseline values was not statistically significant ($p = 0.55$) between Group 1 and Group 2 after the four-week intervention period.

4.3.3.2. The Mini-Mental State Examination

(1) Results of the Mini-Mental State Examination over the four-week intervention period

Results of the MMSE over the four-week intervention period are displayed in Table 4.9.

Table 4.9. Results of MMSE over the four-week intervention period of Group 1 and Group 2

MMSE	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	21.0 [18.0; 24.2]	21.0 [19.5; 23.0]	21.5 [17.0; 25.0]	0.98
Week 1	23.0 [21.0; 24.2]	23.0 [21.8; 25.0]	22.5 [19.0; 24.2]	0.23
Week 2	23.5 [21.0; 25.0]	23.5 [21.0; 25.5]	23.5 [21.8; 25.0]	0.88
Week 3	23.5 [23.0; 26.0]	25.0 [23.0; 26.2]	23.0 [22.8; 24.0]	0.07
Week 4	24.0 [23.8; 26.0]	24.5 [24.0; 26.2]	24.0 [22.8; 25.0]	0.15

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.9. For comparisons between groups at weekly assessments, Mann Whitney U tests were completed without adjustment for multiple comparisons. The MMSE score of participants in Group 1 and Group 2 at baseline was fairly similar. No statistical difference was noted on the MMSE at baseline between Group 1 and Group 2 ($p = 0.98$). The implications of this baseline MMSE score is that the level of cognitive impairment observed in the two groups was similar at the beginning of the study. Based upon the interpretation of the MMSE scores, participants in both groups suffered from mild cognitive impairment at the beginning of the study (baseline).

The level of cognitive impairment in participants from Group 1 and Group 2 improved over the four-week intervention period. For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the

mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks between the groups at week four (4) was not significant (p= 0.096) after adjusting for matching and baseline values. However, participants' MMSE scores at baseline (week 0) and four (4) weeks were further compared with a reference group based on age and education level (Crum et al, 1993).

(2) The Mini-Mental State Examination scores compared to a reference group based on age and educational level

Participants' MMSE scores at baseline (week 0) and four (4) weeks were compared with a reference group based on age and education level (Crum et al, 1993) (Table 4.10).

Table 4.10. MMSE scores at baseline level compared to a reference group based on age and educational level of Group 1 and Group 2 at baseline and week four (4) (Crum et al, 1993)

PARTICIPANTS	BASELINE MMSE score correlate with age and educational-level norm	BASELINE MMSE score does not correlate with age and educational-level norm	WEEK 4 MMSE score correlate with age and educational-level norm	WEEK 4 MMSE score does not correlate with age and educational-level norm
Group 1 (n = 12)	*n* = 2	*n* = 10	*n* = 8	*n* = 4
Group 2 (n = 12)	*n* = 2	*n* = 10	*n* = 4	*n* = 8

The MMSE scores compared to the norm for age and educational level were equal between Group 1 and Group 2 at baseline. Interpretation of the level of cognitive

functioning observed in both Group 1 and Group 2 indicated that two-thirds (66.67%) of participants in Group 1's functioning on cognitive level improved compared to only one third (33.33%) of participants from Group 2's cognitive functioning improved over the first four (4) weeks of intervention.

4.3.4. Results of the assessment of participants' level of anxiety and depression

4.3.4.1. The Hospital Anxiety and Depression Scale

(1) Anxiety subscale over the four-week intervention period

Results of the anxiety and depression subscales over the four-week intervention period are displayed in Table 4.11.

Table 4.11. Results of the anxiety and depression subscales of participants from Group 1 and Group 2 over the four-week intervention period

Anxiety subscale	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	10.0 [6.8; 12.2]	9.5 [5.8; 13.2]	10.0 [7.8; 11.2]	0.91
Week 1	10.0 [5.5; 11.0]	9.0 [6.8; 11.0]	10.5 [4.0; 11.2]	0.79
Week 2	9.0 [3.8; 11.0]	7.0 [4.5; 10.2]	10.0 [3.8; 11.0]	0.58
Week 3	7.0 [3.8; 9.0]	7.5 [3.0; 9.5]	6.0 [4.8; 8.2]	0.66
Week 4	6.0 [4.8; 11.0]	4.5 [2.0; 10.2]	7.0 [6.0; 11.0]	0.17

Depression subscale	[ALL]	Group 1	Group 2	
	n=24	n=12	n=12	
	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	Median [25th; 75th percentiles]	p.overall
Baseline	8.0 [5.8; 10.2]	8.0 [3.8; 10.2]	8.5 [6.0; 9.8]	0.64
Week 1	8.0 [4.0; 11.2]	6.0 [3.8; 12.2]	9.5 [5.5; 11.0]	0.51
Week 2	10.0 [6.0; 11.2]	7.0 [5.8; 10.5]	10.5 [9.8; 11.2]	0.23
Week 3	9.5 [4.8; 11.2]	5.0 [2.8; 11.0]	10.0 [8.0; 12.2]	0.14
Week 4	8.5 [3.0; 11.2]	4.0 [3.0; 8.2]	11.0 [8.8; 13.0]	0.03

For descriptive purposes it was assumed that given the limited number of participants in each group, all data were non-normally distributed. Group 1 and Group 2 were thus described by means of medians, 25th and 75th percentiles in Table 4.11. For comparisons between groups at weekly assessments, Mann Whitney U tests were completed without adjustment for multiple comparisons. The anxiety and depression subscale scores at baseline was fairly even between Group 1 and Group 2. No statistical difference was noted between the groups with regard to their level of anxiety ($p = 0.91$) and depression ($p = 0.64$) at baseline. Based on the interpretation of the anxiety and depression subscales at baseline of participants in Group 1 and Group 2 were indicative of the presence of anxiety and depression in both groups at the beginning of the study.

The anxiety and depression subscale scores of participants in Group 1 and Group 2 improved over the four-week intervention period. No statistical difference was noted on the anxiety subscale score between Group 1 and Group 2 after the intervention period of four (4) weeks ($p = 0.17$). The difference on ranks adjusted for matching and baseline values was not statistically significant ($p = 0.10$) between Group 1 and

Group 2 after the four-week intervention period. The level of anxiety post-intervention was fairly equal in participants from both groups.

A statistical difference was noted on the depression subscale between Group 1 and Group 2 after the intervention period of four (4) weeks ($p = 0.03$). For comparing outcomes at week four (4) adjusting for baseline values as well as the fact that subjects were matched, the mixed model rank ANCOVA analysis was used where the week four (4) and baseline values were ranked and the ranked values were used in the regression analyses. Thus, comparing the difference on ranks adjusted for matching and baseline values was statistically significant ($p = 0.02$) between Group 1 and Group 2 after the four-week intervention period. Participants from Group 1's level of depression improved over the four-week intervention period. However, the level of depression in participants from Group 2 increased over the intervention period. The depression subscale score after the four-week intervention period indicated the probable presence of a mood disorder in seven (7) participants in Group 2. Participants from Group 1 demonstrated a decreased level of depression compared to participants from Group 2 after the intervention period.

4.4. Results gathered at week eight (8), week twelve (12), week sixteen (16) and week twenty (20) of participants in Group 1 and Group 2

As result of the small sample group at week eight (8), week twelve (12), week sixteen (16) and week twenty (20), these results were not discussed in this chapter because no valid conclusions can be drawn from these results. Results gathered at week eight (8), week twelve (12), week sixteen (16) and week twenty (20) are, however, presented in Addendum 14.

4.5. Conclusion

In Chapter 4 the demographical data of the participants who participated in this clinical trial and the results of the outcome measures at the pre-determined times during the intervention were described. The participants in the study's functional progress on body impairment level (King-Devick Test ©, Star Cancellation Test, Mini-Mental State Examination and the Hospital Anxiety and Depression Scale) and functional activity level (Stroke Activity Scale, Barthel Index and the Timed Up and Go Test) were assessed and documented on a weekly basis during the four-week intervention period.

A large number of participants were lost to follow-up following discharge from the TRC after the intervention period of four (4) weeks. Contributing factors to the large number lost to follow-up from week eight (8) to week twenty (20) were:

(1) A few participants returned to work and were unable to attend post-discharge follow-up assessments at TRC.

(2) A small number of participants moved from their local residential areas to family members a great distance from TRC and were therefore unable to travel to and from TRC.

(3) Other participants reported that there were no caregivers available to accompany him/her to and from TRC by means of public transport to attend the follow-up appointment.

(4) A large number of participants changed their contact details after discharge from TRC. The researcher was unable to contact the participants to arrange post-discharge follow-up assessments from week eight (8) to week twenty (20). The social worker at TRC was approached for updated contact details and in some cases no additional information was available.

(5) One (n = 1) participant attended physiotherapy as an out-patient at a governmental hospital setting close to her residence, accompanied by her spouse. The participant reported that she and her spouse were unable to travel to and from TRC for post-discharge follow-up assessments, as her husband was unable to take time off from work additional to the once weekly out-patient physiotherapy sessions close to home. The participant was unable to travel independently.

In Chapter 5, the results and findings of the trial will be discussed in the context of relevant literature. The conclusion of the effect of saccadic eye movement training with visual scanning exercises integrated with task-specific activities on the post-stroke functional outcome of participants that presented with unilateral spatial inattention, visual-spatial disorders and visual-constructive disorders after four (4) weeks of rehabilitation will also be discussed in Chapter 5.