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Faculty of Health Sciences
School of Health Care Sciences
Department of Physiotherapy

**COMPARISON OF VIRTUAL REALITY THERAPY AND
CONVENTIONAL THERAPY ON UPPER LIMB FUNCTION AND
OCULAR TRACKING ON INDIVIDUALS WITH PARKINSON'S
DISEASE: A SINGLE-BLIND RANDOMISED CONTROL STUDY**

A dissertation submitted in fulfilment of the requirements for the degree of Master in
Physiotherapy in the Department of Physiotherapy, Faculty of Health Sciences, University of
Pretoria

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Degree: Masters of Physiotherapy (dissertation)
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Date: October 2016

DECLARATION

I declare that the study entitled “Comparison of virtual reality therapy and conventional therapy on upper limb function and ocular tracking on individuals with Parkinson’s disease: a single-blind randomised control study” is my own, original, work. It has not been previously submitted to this university or any other university for any purposes or for the purposes of acquiring a degree. Where other people’s work has been used (either from a printed source, the internet or any other source), this work has been properly acknowledged and referenced in accordance with the University of Pretoria’s requirements.

Rozelle Cochrane

Signature of Student:



Date: October 2016

LETTER FROM LANGUAGE EDITOR

wordsm;ths
english consultancy

TO WHOM IT MAY CONCERN

I, Barbara English, declare that I have done the language editing on Rozelle Cochrane's Masters thesis.

I make this declaration with the understanding that the candidate herself is responsible for the final condition and submission of her thesis.

Barbara English

14 June 2016

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Lastly, the author thanks her family and friends, who have supported her every single step of the way. May God continue to make you a blessing to others as well.

ABSTRACT

Background:

Parkinson's disease (PD) is a debilitating progressive neurological disorder. The main clinical features of PD are: rigidity, bradykinesia, akinesia, and resting tremor. People living with PD often present with impaired gross- and fine upper-limb motor control and ocular tracking. The impaired motor control associated with PD results in difficulty performing basic- and instrumental activities of daily living (BADLs and IADLs). Virtual reality (VR) therapy is an emerging treatment strategy used to address movement impairment in people with neurological diseases, but has not been extensively researched in the rehabilitation of people with PD. This study aimed to determine the effectiveness of VR therapy as a treatment modality for the rehabilitation of upper-limb function during BADLs and IADLs and ocular tracking for people with PD, when compared to conventional physiotherapy.

Methods:

A single blind randomised control trial was done. Participants were randomly allocated to either the conventional therapy (control) or VR therapy (experimental) groups using the concealed opaque envelope method. Twenty-two participants who gave informed consent were included, if they met the following criteria: Confirmed PD diagnoses; scored above 24/30 for the Mini Mental State Examination; and did not suffer from uncontrolled co-morbid diseases. The control- and experimental groups underwent twelve intervention sessions of 45 minutes. The control group participated in conventional physiotherapy sessions and the experimental group used the X-box Kinect® VR apparatus during treatment. Participants were assessed at baseline and post-intervention (directly following the 12 sessions) with the: 9 Hole Peg Test (9HPT), Test d'Evaluation des Membres Superieurs De Personnes Agees (TEMPA) and the King Devick Test.

Results:

The TEMPA was used to determine unilateral- and bilateral upper-limb function during IADLs and BADLs. Three of the four items of the TEMPA that assessed bilateral upper-limb function indicated statistically significant improvement when the difference between the control and experimental groups were compared post-intervention (Task1 $p=0.611$; Task 2 $p=0.0043$; Task 3 $p=0.0078$; Task 4 $p=0.0002$).

Similarly, three of the four items of the TEMPA that assessed unilateral upper-limb function indicated statistically significant improvement for the experimental group, when compared to the control- group post-intervention (Task 5 $p=0.0151$; Task 6 $p=0.4118$; Task 7 $p=0.0064$; Task 8 $p=0.0009$). The 9HPT assessed in-hand manipulation and fine upper-limb function. Results from the 9HPT for the left- and right hands of both groups showed clinically significant improvements from baseline to post-intervention, but there was no statistically significant difference between the two groups. The King Devick test was used to assess ocular tracking. The comparison of change between the two groups from baseline to post-intervention on the King Devick did not indicate clinically- or statistically significant change.

Discussion and Conclusion:

The findings from the bilateral IADL and BADL tasks as measured with the TEMPA are similar to findings in the literature. The results show that VR therapy improve motor control of the upper-limb significantly when both hands work together and when the upper-limbs are moving unilaterally. VR therapy might be more effective than conventional physiotherapy because it allowed for repetitive practice of functional activities, which aided the development of limb control and functional muscle strength. The VR therapy also allowed task-oriented training to occur repetitively. Task-oriented training is known to aid neural plasticity and facilitate functional rehabilitation. The insignificant differences between the groups on the 9HPT is an indication that the task performed for this outcome measure is not specific enough to detect hand function and grip strength. The King Devick test did not indicate change for the control- or experimental groups, which indicates that specific ocular tracking exercises should be included in therapy to address this impairment.

Keywords: Parkinson's disease, upper-limb function, virtual reality therapy, activities of daily living, basic activities of daily living and instrumental activities of daily living, ocular tracking.

PUBLICATIONS AND PRESENTATIONS IN SUPPORT OF THIS DISSERTATION

STUDY OUTPUTS: PRESENTATIONS

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ABBREVIATIONS

Abbreviation	Description
9HPT	9 Hole Peg Test
ADL	Activity of Daily Living
BADL	Basic Activity of Daily Living
CONSORT	Consolidated Standards of Reporting Trials
CVI	Cerebro-vascular Incident
IADL	Instrumental Activity of Daily Living
ICF	International Classification of Health, Disability and Function
MMSE	Mini Mental State Examination
MS	Multiple Sclerosis
PD	Parkinson's Disease
QOL	Quality of Life
RCT	Randomised Control Trial
SD	Standard Deviation
TBI	Traumatic Brain Injury
TEMPA	Test d'Evaluation Des Membres Superieurs de Personnes Agees
VR	Virtual Reality

CHAPTER 1

INTRODUCTION

1.1 Introductory Background and Orientation to the Study

Parkinson's Disease (PD) is a debilitating progressive neurological disorder that affects about 3% of people in the over-60 age group in South Africa (Carr, Kies, Fine and the Movement Disorders Group of South Africa 2009:755). This multisystem disorder affects the motor-, sensory- and cognitive systems (Braak, Ghebremedhin, Rub, Bratzke and Tredici 2004:124). Parkinson's Disease is categorised in the literature as a movement disorder because the movement impairment is the most frequently observed clinical symptom (Dubois, Burn, Goetz, Aarsland, Brown, Broe, et al 2007:2315). Parkinson's Disease occurs due to degeneration of the basal ganglia (Calabresi, Picconi, Tozzi, Ghiglieri and Di Filippo 2014:1023). It is the second most prevalent neurological disease after stroke and the fourth most common neurodegenerative disease in the elderly. The main clinical features of PD are: rigidity, bradykinesia and akinesia, and a resting tremor (Umphred, Lazaro, Roller and Burton 2013:601-2). People living with PD may present with impaired trunk control, ocular tracking and gross and fine upper- and lower limb movements as well (Umphred, et al 2013:601).

Persons living with PD present with movement impairments that interfere with their ability to perform basic activities of daily living (BADLs) as well as instrumental activities of daily living (IADLs) (Millan-Calenti, Tubio, Pita-Fernandez, Gonzalez-Abraldes, Lorenzo, Fernandez-Arruty, et al 2010:306-7). "Basic activities of daily living" (BADLs) refer to all grooming-, self-care- and eating tasks. Instrumental activities of daily living (IADLs) are all activities that involve the handling of apparatus or instruments (Millan-Calenti, et al 2010:307). Parkinson's Disease affects both gross- and fine upper limb control and leads to severe impairments during BADLs and IADLs, which impact on the quality of life (QOL) of the person living with PD.

The movement impairments caused by PD will become more pronounced as the disease progresses. With disease progression it becomes more difficult for sufferers of PD to perform activities of daily living (ADLs), which affects not only the person's QOL, but also the QOL of significant others, including family members and caregivers (Carter, Lyons, Lindauer and Malcolm 2012:15).

Various disability models (Shumway-Cook and Woollacott 2007:143-4) or disablement/enablement models (Umphred, et al 2013:607-8) have been described for the purpose of enabling therapists to understand the interaction between disease, disability and treatment goals for patients with PD. The role of conventional physiotherapy, specifically for treating PD, is to retain the person's ability to perform a wide range of ADLs for as long as possible in order to optimise their independence as well as their QOL (Hariz and Forsgren 2011:25-6). Physiotherapy aims to enable people living with PD to perform ADLs independently at home, as well as to maintain their independence by teaching them strategies that they can use for making daily living easier at home (Hariz, et al 2011:25-6).

In a study designed to assess upper limb function, Klockgether and Dichgans (1994:54-5) found that ocular tracking plays a big role in upper limb movement accuracy and speed. Ocular tracking is defined as the eyes' ability to track movement while the head maintains a static position. Ocular tracking occurs naturally while a person looks at the activity of the hand (Johansson, Westling, Backstrom and Flanagan 2001:6920). The ability to perform ocular tracking has a direct impact on people's co-ordination of movement when they perform upper limb tasks (Johansson, et al 2001:6923-4). When ocular tracking exercises are included as a treatment modality during rehabilitation, there is a marked improvement in the quality, as well as co-ordination, of upper limb movement (Klockgether, et al 1994:54-5). An improvement in the quality of movement and co-ordination leads to an improvement of the performance of ADLs.

1.2 Physiotherapy Interventions for Patients with Parkinson's Disease

Conventional therapy indicated for people living with PD includes: stretching; strengthening; co-ordination; postural control; block practice; verbal cueing; and group classes (Schmitz-Hubsch, Phyfer, Kielwein, Fimmers, Klockgether and Wullner 2005:543; Tamir, Dickstein and Huberman 2007:68; Stack, Roberts and Ashburn 2012:3-4; Tomlinson, Patel, Meek, Clarke, Stowe, Shah, et al 2012:3). One of the new treatment strategies used by physiotherapists to improve ADLs in people living with neurological conditions is virtual reality (VR) therapy.

Virtual reality (VR) therapy is the implementation of specialised computer programs, presented in a gaming forum, which is implemented in the use of rehabilitation. This type of therapy allows the creation of an artificial environment, where a patient can freely and safely explore movement. The VR apparatus used for this study is an X-Box Kinect system. The X-Box Kinect VR system consists of a console, remote and a monitor (television) screen. The console detects movement and transmits the movement to the screen. When the person moves his/her body the avatar (virtual character on the screen) moves in unison with the person, and allows him or her to complete a specific virtual task. The task is thus performed by the person and the image mirrored on the television screen. Virtual reality therapy is a relatively new treatment concept that was implemented for the first time for people living with PD in 1998 (Rovetta, Lorini and Canina 1998:180-1). Implementation of VR therapy has proven to produce significant improvement in upper limb function in people living with traumatic brain injuries (TBIs) and people living with cerebro-vascular injuries (CVIs) (Henderson, Korner-Bitensky and Levin 2007:59-60; Saposnik, Teasell, Mamdani, Hall, McIlroy, Cheung, et al 2010:1480). However, limited research about the effectiveness of VR therapy for people living with PD is available.

Despite the limited research that is available on the effect of VR in the treatment of PD, studies that have been conducted show promising indications for the use of VR. Virtual-reality-based-therapy has been used to improve PD patients' abilities to perform shopping tasks and fine hand manipulation activities (Rovetta, et al 1998:180-1; Tarr and Warren 2002:1090).

The research that has been done is, however, limited by small sample sizes and the VR systems that were implemented were not easily accessible to patients (Rovetta, et al 1998:181; Tarr, et al 2002:1091).

1.3 Problem Statement

People living with PD struggle to perform BADLs and IADLs and feel shy about their lack of motor control, making them reluctant to leave their home environments (Martinez-Martin, Rodriguez-Blazquez, Kurtis, Chaudhuri and the NMSS Validation Group 2011:400). This study was conceptualised to determine the effectiveness of VR therapy as a treatment modality for upper limb function and ocular tracking for people living with PD, in order to enhance the performance of BADLs and IADLs.

Virtual-reality therapy is an emerging treatment strategy used to address movement impairment in people living with a neurological disease, but has not yet been researched widely in the rehabilitation of people living with PD.

Commercially available VR apparatus has the potential to be a valuable tool in the rehabilitation process. Virtual-reality therapy is not only cost effective, but it can also be done regularly, at convenient times, and as a leisure activity. Using the VR apparatus can be enjoyable and patients can compete against their own ability as a continuous motivating factor (De Mauro, Ardanza, Monge and Rueda 2013:1). Research indicates that continuing with therapy enables people living with PD to be more independent indefinitely, if they can afford the cost (Tomlinson, et al 2012:15). The researcher questioned whether treatment with freely available VR apparatus (such as the X-box[®]) would be effective in improving upper limb motor control and ocular tracking in people living with PD. If the VR therapy with the X-box[®] is found to be effective, it may be prescribed to PD patients as a home-based exercise strategy. By providing PD patients with an inexpensive, easy-to-use home-based supplementary treatment regime, patients can reduce the number of out-patient therapy appointments and maintain their independence for longer. The use and effectiveness of this apparatus, however, need to be examined further.

1.4 Significance of the Study

The aim of the study was to determine if treatment with an X-Box Kinect® would improve gross- and fine upper limb movement used during ADLs (e.g. dressing, grooming and eating) when compared to regular therapy for people living with PD. Should the results of the study indicate that VR therapy has a positive effect, it might open up new treatment options for people living with PD. The VR therapy might also allow people living with PD to continue therapy at home with a relatively inexpensive device. If the VR therapy proves to be effective it will improve the upper limb function of people living with PD, allowing them more independence and better QOL. Virtual-reality therapy might also help to slow down functional decline and improve upper limb functional carry over into ADL tasks.

As a physiotherapist working in the field of neurology the principal researcher has used VR therapy (specifically an X-Box) for people living with CVIs, TBIs and Multiple Sclerosis (MS). All of these aforementioned patients who received the VR therapy enjoyed this form of therapy and showed improvement when performing ADLs after the treatment sessions. The researcher experienced that when the VR therapy is carried out as a home exercise, patients allow themselves more intense interventions, as they exercise daily. The patients that were treated with the VR by the researcher (prior to the conduction of this study) were also more compliant with doing their home exercises as they enjoyed the games and could do them with friends and family. The positive experiences of the patients that were treated by the researcher made the researcher keen to try VR therapy on people living with PD.

This study also forms part of a collaboration between the University of Pretoria and the University of Brasilia, in Brazil. The collaborative studies aimed to see whether treatment with freely available VR apparatus would be an effective modality to use during therapy at home and during physiotherapy treatment sessions for people living with PD.

The research conducted at the University of Pretoria focused on upper limb function and ocular tracking. University of Brasilia focused their research on lower limb function and ocular tracking in patients with PD.

Feedback regarding the results of both studies was shared between the two universities. The aim of continual research in the field of physiotherapy is to find new treatment strategies. These strategies could contribute towards the improvement and maintenance of people living with PD's motor control and functional abilities.

1.5 Research Question, Hypotheses, Aim and Objectives

1.5.1 Research Question

What is the effect of VR training on gross- and fine upper limb function and ocular tracking of individuals living with PD when compared to conventional physiotherapy?

1.5.2 Hypotheses

H1

There would be a significant difference between the results of 12 sessions of VR therapy as a treatment modality when compared to 12 sessions of conventional physiotherapy, with regard to gross- and fine upper limb motor function and ocular tracking, during IADLs and BADLs in people living with PD.

H0

There would be no significant difference between the results of 12 sessions of VR therapy as a treatment modality when compared to 12 sessions of conventional physiotherapy, with regard to gross- and fine upper limb function and ocular tracking, during IADLs and BADLs in people living with PD.

1.5.3 Aim of the Study

To determine if VR therapy as a treatment modality is more effective than conventional physiotherapy in people living with PD with regard to upper limb function and ocular tracking during IADLs and BADLs.

1.5.4 Objectives

The objectives of the study were to:

- Establish the demographic profile (e.g. age, gender and date of onset of the disease) of the participants by means of a demographic questionnaire;
- Determine fine upper limb motor control before, during and directly after the intervention by means of the 9 hole peg test (9HPT);
- Determine the quality of functional upper limb movement before, during and after the intervention by means of the Test d'Evaluation des Membres Superieurs De Personnes Agees (TEMPA);
- Assess ocular tracking before, during and after intervention by means of the King Devick test;
- Determine if VR therapy as a treatment modality is an effective treatment modality for people living with PD;
- Determine if VR therapy is more or equally as effective as conventional physiotherapy in people living with PD with regard to upper limb function during IADLs and BADLs; and
- Determine if VR therapy is more or equally as effective as conventional physiotherapy in the improvement of ocular tracking in people living with PD.

1.6 Delimitations and Assumptions

The delimitations and limitations of the study were:

- Functional carry over surpassing six weeks was not determined in this study as it was not one of the objectives.
- The sample recruited for the study was limited to people living with PD in the Bryanston area and not the whole of Gauteng Province, as the practice where the study was conducted was based in Bryanston and it was convenient for the participants to access the facility.

The assumptions of the study were:

- That people living with PD within the Bryanston area were interested in participating in the study; and
- That the X-Box Kinect[®] was easy for participants to understand and use during the study.

1.7 Clarification of Terminology

1.7.1 Functional Carry Over

The carry over effect is defined as “*any situation in which an individual’s previous history and experience explains their current performance in a given situation*” (O’Connor, Norris, Crossin and Cooke 2014:1). For this study functional carry over was defined as the ability to retain a motor skill between practice sessions or to transfer a learnt movement into a functional task.

1.7.2 Ocular Tracking

Ocular tracking is defined as the ability of the eye to maintain a point of gaze, or the motion of the eye in relation to the position of the head (Karthikeyan, Jagadeesh, Shenoy, Ecksteinz and Manjunath 2013:625-6).

1.7.3 Parkinson’s Disease

The Parkinson’s Disease Foundation (http://www.pdf.org/about_pd) defines PD as a “*chronic and progressive movement disorder, meaning that symptoms continue and worsen over time*”.

1.7.4 Therapy

‘Therapy’ is a broad term that is used to describe the “*treatment of disease or disorder, as by some remedial, rehabilitating, or curative process*” (<https://www.dictionary.com/browse/therapy>).

1.7.5 Upper Limb

The upper limb is the region in humans that extends from the deltoid to the hand, and includes the shoulder, upper arm, elbow, lower arm, wrist, hand and fingers (Farlex Partner Medical Dictionary, <http://www.medical-dictionary.thefreedictionary.com/upper+extremity>).

1.7.6 Virtual Reality

The Merriam-Webster dictionary defines VR as: “*an artificial environment which is experienced through sensory stimuli (as sights and sounds) provided by a computer and in which one’s actions partially determine what happens in the environment*” ([http://www.merriam-webster.com/dictionary/virtual reality](http://www.merriam-webster.com/dictionary/virtual%20reality)).

1.8 Outline of Dissertation Chapters

In this chapter (Chapter One), the introduction to the study was presented and the background and problem statement of the study were set out. The research questions, aims and objectives of the study were explicated, as well as the importance and benefits of the study. A review of the current literature and the limitations that were observed in the available literature is discussed in Chapter Two. The structure of the literature review is based on the International Classification of Health, Disability and Function (ICF) model.

The methodology that was used during the execution of this study is described in Chapter Three. The results, which include pi-charts, tables and graphs, are set out in Chapter Four. The discussion of these results is presented in Chapter Five. The limitations that were experienced during the execution of this study as well as recommendations for future research are also presented in Chapter Five. The implications of the study for people living with PD is presented in the conclusion, at the end of Chapter Five. The outline of the dissertation is illustrated in Figure 1.1.

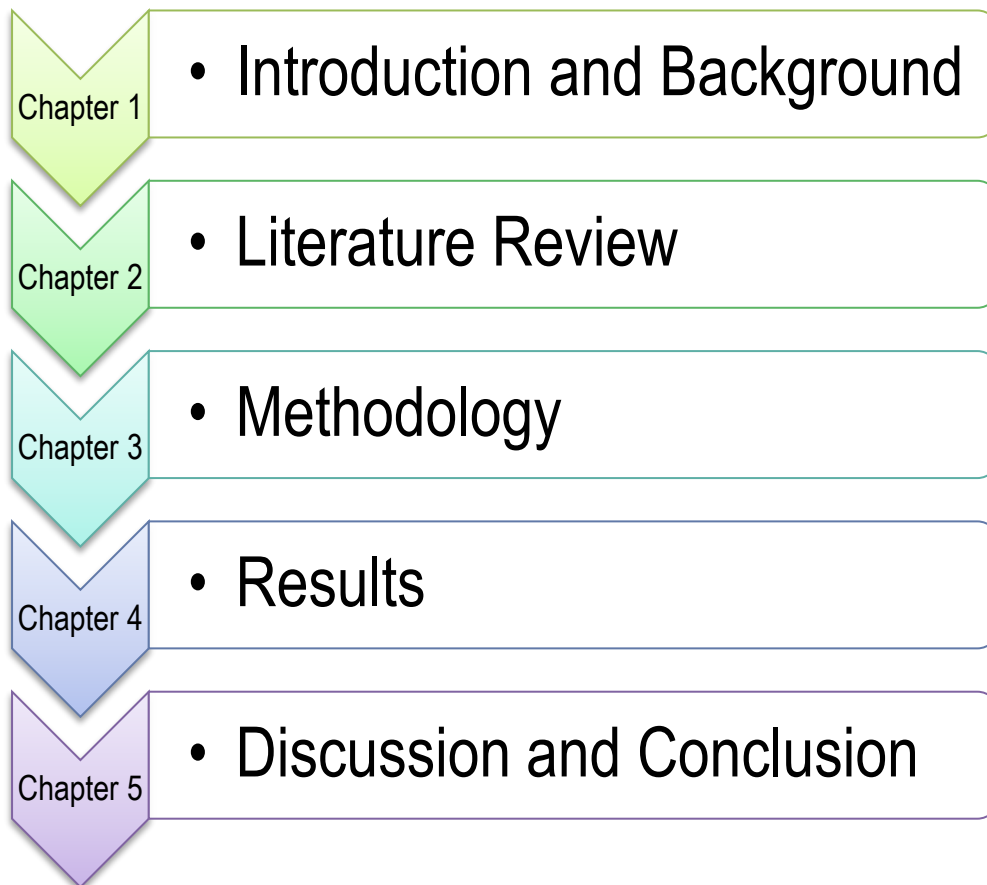


Figure 1.1 Outline of the Dissertation

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Chapter One set out the background to the study and the research question and hypothesis. The aims, objectives and general outline of the dissertation were also presented in Chapter One. In this chapter the literature that is relevant to the study is reviewed and discussed in detail. The search strategies that were used to identify the relevant literature are also indicated in this chapter. The literature review helps to identify the incidence of PD, as well as the motor control impairments that patients with PD live with. The motor control components that are focused on in the review are the upper limb- and ocular tracking that are required during the performance of normal ADLs. The effect of motor control impairments on QOL is also explored in this review. The literature review also aims to explore the use of VR therapy in clinical practice. The limitations that have been identified in the usage of VR therapy are also indicated in the review. Gaps in the current literature are exposed and the researcher indicates how this study aims to fill those gaps.

The International Classification of Health, Disability and Function (ICF) framework (illustrated in Figure 2.1) was used as the theoretical framework on which this review is based.

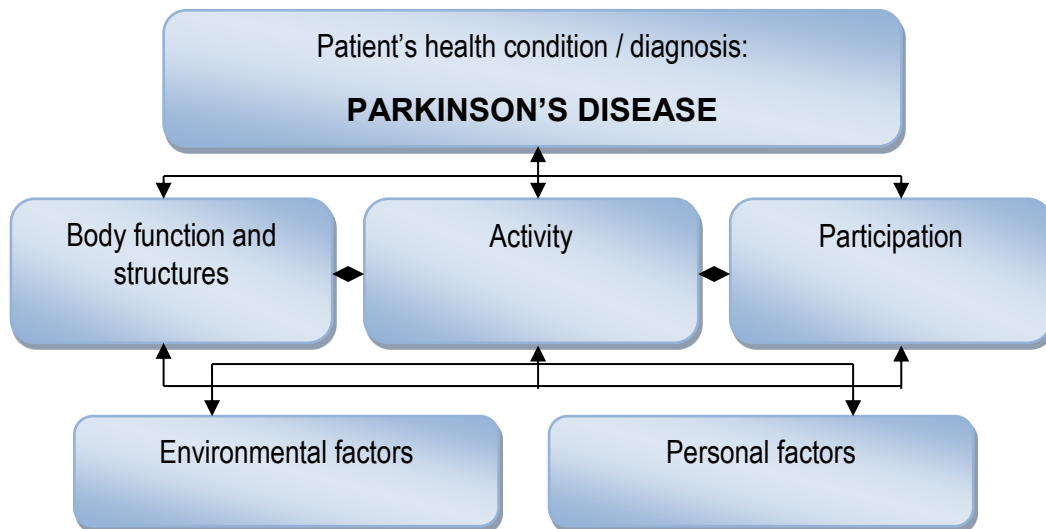


Figure 2.1 ICF Framework (World Health Organisation International Classification of Functioning, Disability and Health Model, WHO 2001)

2.2 Literature Search and Search Strategy

In order to identify relevant literature pertaining to the topic, an electronic search was performed of PubMed, PEDro, CINAHL, Google Scholar, Medline and the Cochrane Database of Systematic Reviews databases for articles published between the dates of January 2001 to February 2016.

The following search limits were set for the electronic search: participants in studies encountered had to have been human subjects; articles had to have been published in the English language; and adult subjects (>18 years) had to have been the focus of the investigations.

The key words that were used during the execution of the searches were: “Parkinson’s Disease”; “bradykinesia”; “upper limb”; “function”; “akinesia”; “rehabilitation”; “exercise”; “neurology”; “rehabilitation”; “tremor”; “vision”; “ocular tracking”; “virtual reality”; and “simulated environments”. The key words were searched for in all possible combinations.

Once a comprehensive list of articles was obtained, duplications were removed and the titles of the articles were screened to determine if the articles were relevant to the study. The abstracts of the studies that were identified from the title searches were reviewed and, in total, 1 830 full-text articles were retrieved. Reference lists of appropriate studies were also hand-searched to identify further studies for potential inclusion. This search method identified 57 relevant articles, which were included in the review process (Figure 2.2).

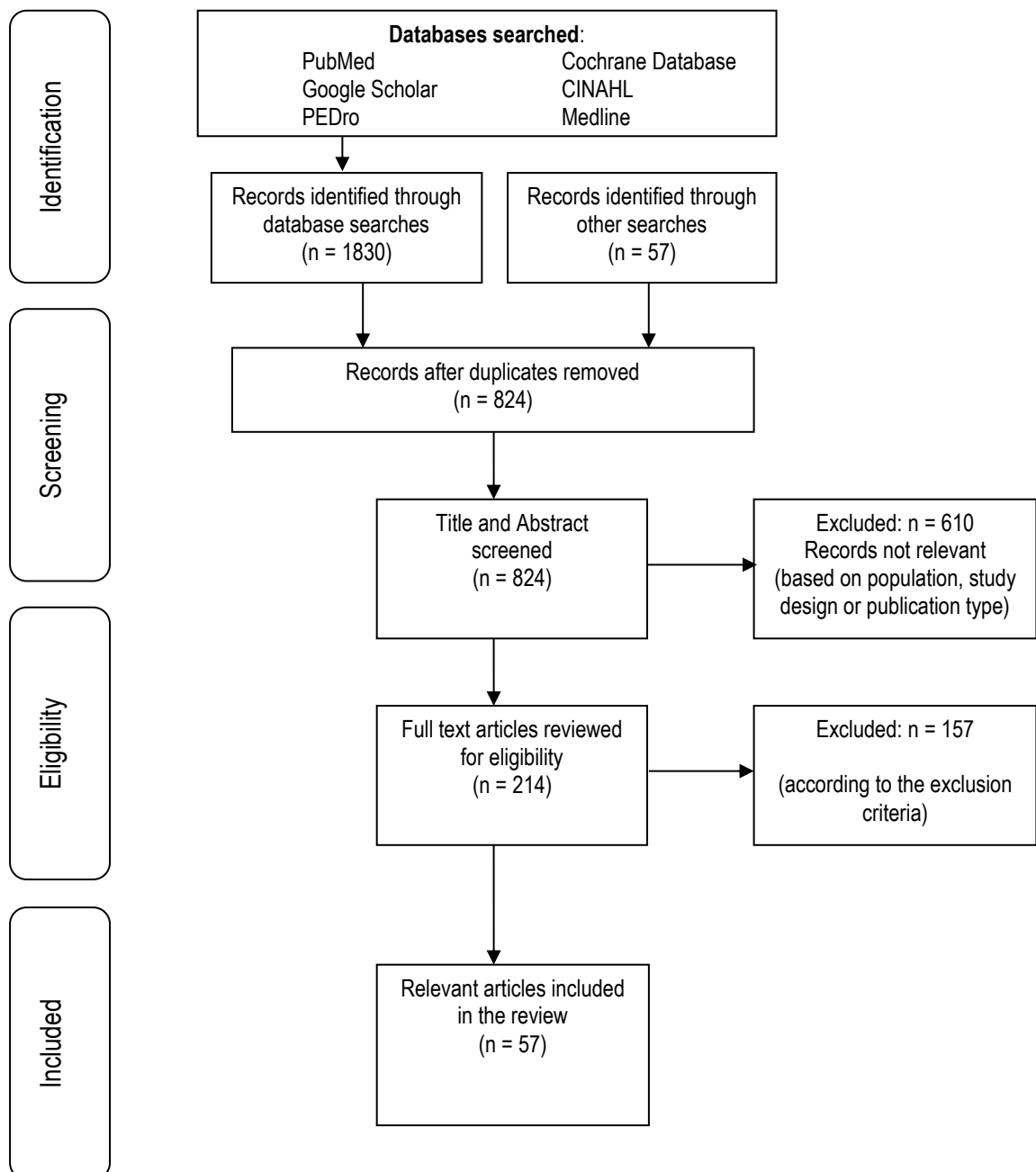


Figure 2.2 Literature Review Search Strategy Flow Chart (Based on the PRISMA Flow diagram, Moher, Liberati, Tetzlaff, Altman and PRISMA group 2009:267)

2.3 Parkinson's Disease

In order to gain a comprehensive view of PD, a theoretical framework was created based on the articles identified by the literature search and the ICF.

2.3.1 The Theoretical Framework

The theoretical frame work consists of the features that have been set out below.

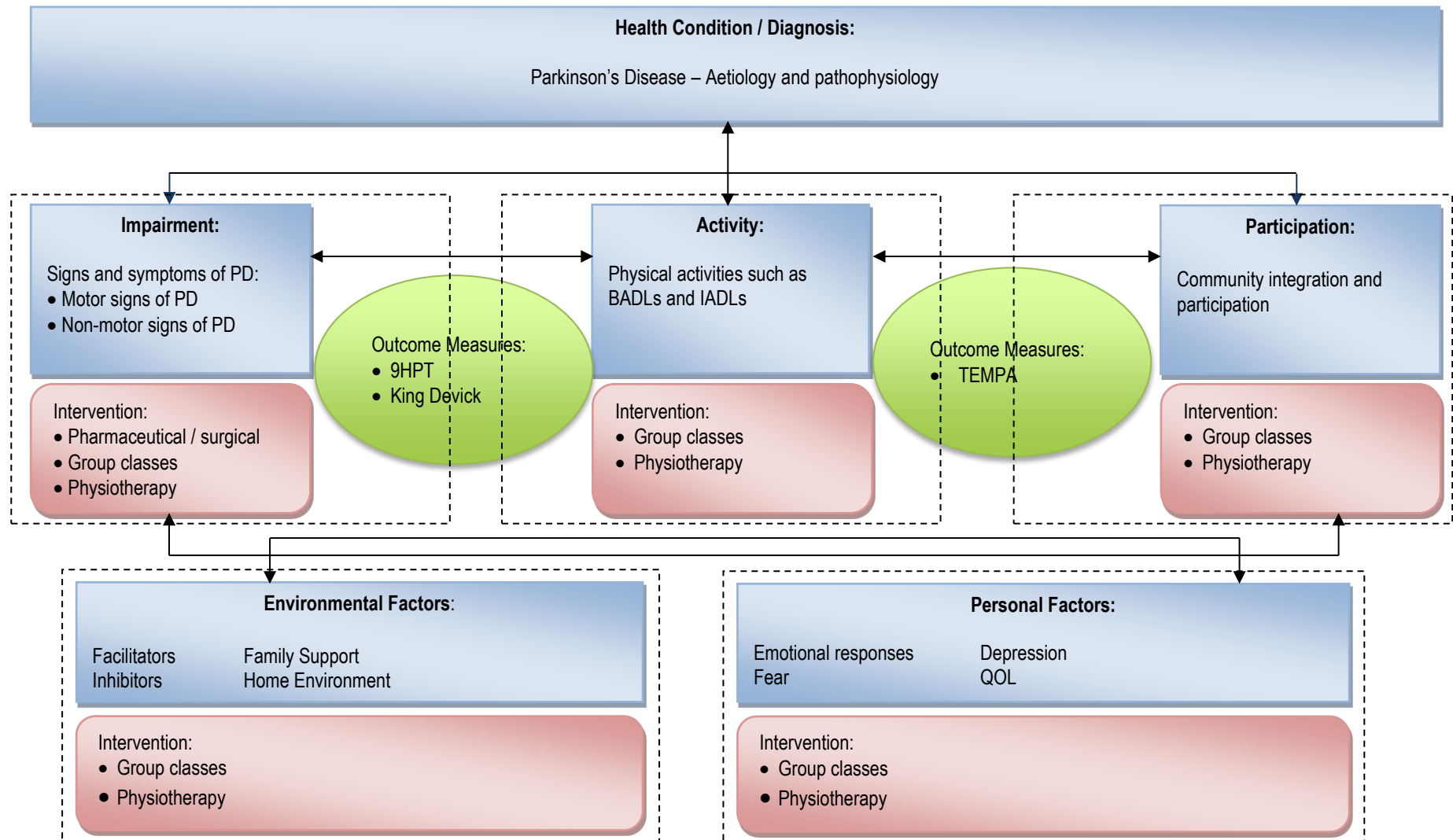
- The aetiology and pathophysiology of PD ('health condition' according to the ICF). This section of the review describes the global effect of PD on the basis of the latest statistics available on the prevalence of the disease. The pathophysiology gives a clear picture of which neural structures are impaired when a patient lives with PD and how the physical symptoms can be relayed back to the injured structures.
- The signs and symptoms of PD ('impairments' according to the ICF). Although it is important to understand the pathophysiology underlying PD, the disease is clinically diagnosed by the physical symptoms rather than the pathophysiological signs. Therefore, the literature review has described the signs and symptoms as well.
- The effect of PD on functional activities such as BADL and IADL ('activity' and 'participation' according to the ICF). The impact of PD on functional tasks leads to the discussion on the implications of limitations PD patients experience during participation in everyday tasks ('participation' level according to the ICF).
- Personal and environmental factors. People living with PD are known for becoming withdrawn from the community. The social withdrawal may be due to environmental factors such as poor accessibility to public places or this withdrawal might be due to physical and emotional factors. The difficulties experienced with ADLs could also result in depression and anxiety. The literature review discusses these different factors to help identify areas where therapy can help people living with PD to become more independent and, as such, experience better QOL.

- In addition to the components of the ICF, the current rehabilitation techniques used for people living with PD and the outcome measures to help monitor whether the rehabilitation technique is effective or not, are discussed as well.
- Lastly, the literature review describes the limitations found in the current physiotherapy treatment regimes.

The theoretical framework on which the literature review is based is graphically represented below in Figure 2.3. This framework is based on the model by McGaghie, Bordage and Shea (2001:923-4) and Angeloni (2013:3).

The key for the interpretation of Figure 2.3 is as follows:

- The ICF components that are affected in patients living with PD are indicated in **blue**.
- The effect of physiotherapy and potential effect of VR therapy on the ICF components is indicated in **pink**.
- The outcomes measures used to establish the effect of the conventional physiotherapy when compared to VR therapy, for the different aspects of the ICF, are indicated in **green**.



*PD – Parkinson's Disease; BADLs – Basic Activities of Daily Living; IADLs – Instrumental activities of daily living; QOL – Quality of Life; 9HPT – 9 Hole peg test; TEMPA – Test d'Evaluation des Membres Superieurs De Personnes Agees.

Figure 2.3 Theoretical Framework of the Literature Review

2.3.2 Parkinson's Disease Incidence, Prevalence and Pathophysiology

Parkinson's Disease is a well-known neurological disease that has been described in Chinese medicine as far back as 2500 years ago (Parkinson's Disease Foundation, https://www.pdf.org/about_pd). James Parkinson first diagnosed the disease as we know it today in 1817 and the disease was initially named after him. Initially, PD was known as "shaking palsy" but was renamed "Parkinson's Disease". Parkinson's Disease has been classified as a neuro-cognitive condition in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM5) (American Psychiatric Association 2013:636). As PD has been a recognised neurological condition since the eighteenth century, numerous studies have been done on the incidence of the disease worldwide.

Incidence

Various studies on the worldwide incidence of PD have been conducted between 1965 and 2010. "Incidence" refers to the number of new cases reported during a specific period in a defined population (Wright, Evanoff, Lian, Criswell and Racette 2010:144). The study by Wright, et al (2010:148) indicated that there has been a steady increase in the incidence of PD since the discovery of the disease, especially amongst the elderly. Although there are correlations in the literature with regard to the increased incidence of PD, the overall estimates differ between different countries (Muangpaisal, Hori and Brayne 2009:282-3).

In North Sweden an epidemiological study conducted over four years assessed the incidence of newly diagnosed neurological conditions and found that the incidence of PD was 19.7 out of every 1 000 000 people (Linder, Stenlund and Forsgren 2010:346-7). The study concluded that the incidence rate among males was slightly higher than that for females, although their findings were not statistically significantly different (men 3.4% and woman 2.6%). A Russian study (Winter, Bezdolnyy, Katunina, Avakjan, Reese, Klotsche, et al 2010:354) found similar results with regard to gender incidence and indicated only a 0.87 difference between the prevalence of PD in males and females.

The gender prevalence were fairly similar, as well as the incidence rate of PD, which was 9.03 out of every 100 000 people over 60 (Winter, et al 2010:354). The aforementioned literature indicates that the number of new cases reported annually in Europe is similar between countries, although the population differs.

Prevalence

“Prevalence” refers to the number of people who have a particular disease at a specific time. Prevalence, therefore, focuses on whether a disease is present at a specific time and not on when the disease occurred ([http://www.medical-dictionary.thefreedictionary.com/Prevalence+\(epidemiology\)](http://www.medical-dictionary.thefreedictionary.com/Prevalence+(epidemiology))). A prevalence study in Buenos Aires indicated that 31.2 out of 100 000 persons are affected by PD per year, with males being less affected than females (1 male: 3 females) (Bauso, Tartari, Stefani, Rojas, Giunta and Cristiano 2012:1111). In Brazil, a study by Barbosa, Caramelli, Maia, Cunningham, Guerra, Lima-Costa, et al (2006:803) produced similar results with 7 of every 100 people over the age of 64 years having either PD or Parkinsonism. In sub-Saharan Africa the prevalence of PD has been documented at a rate of between 7 and 20 per 100 000 people (Blanckenberg, Bardien, Glanzmann, Okubadejo and Carr 2013:23). Although studies documenting the incidence of PD in sub-Saharan Africa could not be found, the results from the prevalence studies are similar in sub-Saharan Africa and Brazil. The similarities between these aforementioned results formed part of the basis of collaboration for this research project.

In South Africa PD affects about 3% of people in the age group over 60 (Carr, et al 2009:755). Prevalence studies that included the entire South African population could not be found in the literature. However, a study that was done in a specific South African community showed that PD is more prevalent among males compared to females (3:1) (Okubadejo, Bower, Rocca and Maragonore 2006:2151). From the literature it can be observed that the prevalence of PD in developing countries is slightly higher than in developed countries, but this may be attributed to the difference in population sizes in the countries. The prevalence of PD between males and females also differs between developed- and developing countries. In order to limit selection bias in this study, males and females were recruited for participation.

Pathophysiology of PD

The control of movement (motor control) is complex and requires multiple structures in the brain to work in synergy to perform any movement (Krebs, Weinberg and Akesson 2012:347-8). If any of the structures in the brain are affected (by disease or injury) motor control will be compromised. The primary motor cortex, the supplementary movement area, the basal ganglia and the cerebellum have to work simultaneously and in a synchronised way during the execution of tasks to ensure that optimal motor control occurs (Krebs, et al 2012:349). The neurons that are located in these brain structures are responsible for signal conduction in specific pathways, which will allow movement to occur. The conducted signals travel from layer V in the primary cortex, through the pyramidal tracts, to the upper motor neurons and interneurons of the spinal cord (Hutchinson, Kimmich, Molloy, Whelan, Molloy, Lynch, et al 2013:1768).

The primary role of the basal ganglia during the execution of motor control is movement co-ordination, muscle tone regulation and postural control regulation. The basal ganglia consist of the telencephalon, diencephalon and mesencephalon. The diencephalon is the region of the basal ganglia in which the substantia nigra is located. Parkinson's Disease is brought on by pathology in the substantia nigra (Hutchinson, et al 2013:1768).

The substantia nigra is located in the cerebral peduncles, on the level of the superior colliculi, and is of clinical importance as it contains the dopaminergic pathway that projects to the putamen and caudate nucleus (Krebs, et al 2012:313). Parkinson's Disease symptoms are caused by the death of the dopaminergic neurons located in the substantia nigra (Alexander 2004:259). The main motor dysfunctions associated with PD are tremors and rigidity. These dysfunctions have been linked to a deficit of dopamine in the posterior putamen and the motor circuit. Other symptoms associated with PD (such as hypokinesia and bradykinesia) might rather be caused by dopamine disruption in structures such as the brainstem and cortical mechanisms. The non-motor deficits or executive deficits (mild cognitive deficits and dementia) are associated with dopamine deficiency in the caudate nucleus and the non-motor circuits (Rodriguez-Oroz, Jahanshahi, Krack, Litvan, Macias, Bezard, et al 2009:1128-30).

The pathophysiology of PD can thus be summarised as damage to the dopamine-producing cells that result in motor control fallouts. Owing to the nature of the condition the degeneration to the dopaminergic pathways or the repair of damage done by PD can never be fully restored. The physical impairments that arise as a result of the degeneration and damage to the dopaminergic pathways are discussed below.

2.3.3 Signs and Symptoms (Impairments) of Parkinson's Disease

Parkinson's Disease is characterised by motor- and non-motor signs and symptoms. The motor symptoms / signs include: hypokinesia (subcategorised as akinesia and bradykinesia); rigidity; tremor; loss of postural reflexes and decreased proprioception (Usui, Hatta, Doi, Kubo, Kamigaichi, Nakanishi, et al 2011:1704-5). In a study by Jankovic (2008:368) it is suggested that because of the limited number of available tests, PD must be diagnosed on the basis of clinical criteria. The study also relied on motor signs to diagnose PD, as the non-motor signs become noticeable only later in the progression of the disease (Jankovic 2008:368).

Motor signs

“Bradykinesia” refers to slowed or decreased movements, which clinically manifests as slow gait with decreased arm swing (Massano and Bhatia 2012:2). Bradykinesia also causes difficulty with the initiation and termination of movement once it has commenced. “Akinesia” on the other hand refers to ‘freezing’ of movement, that can be described as the inability to move voluntary muscles in the limbs as a result of prolonged intervals between the command and the first muscular contraction (Williams, Holtin, Strand, Revesz and Lees 2007:2237). Although freezing is most commonly observed during gait it may occur during bilateral upper-limb activities, such as dressing and eating (Nieuwboer, Kwakkel, Rochester, Jones, van Wagen, Willems, et al 2007:135-6). Both akinesia and bradykinesia are motor-planning deficits where a processing element is the primary cause of the deficit and not just a muscular element.

“Rigidity” refers to the stiffness or inflexibility of the muscle groups found in people living with PD. Rigidity can lead to pain and a fixed-mask-like facial expression (<http://www.parkinsons.org.uk>).

The rigidity seen in people living with PD is non-velocity-dependent hypertonicity that offers either uniform resistance throughout the whole range of motion or a jerky, catch and release type resistance that is commonly referred to as “cog wheel” hypertonicity. Tremors are one of the most common motor signs associated with PD and in 75% of all cases it is the initial clinical sign (Jankovic 2008:369). A tremor is an involuntary shaking movement in a part of the body. The tremors associated with Parkinson’s Disease are mostly resting tremors which is seen in the hands, as a pill rolling action (Jankovic 2008:369). The tremors are exacerbated during upper limb exertion movements or when there is increased tension in the musculature and may ease or even completely stop during sleep and purposeful active movements. Generally, tremors are observed unilaterally in the upper extremities but it may become visible bilaterally with disease progression (Jankovic 2008:370). During advanced stages of PD tremors may also spread to other body parts - including the lower extremities, face, shoulders and neck. The lower limb has less noticeable postural changes during rest but during active tasks, such as gait, shuffling and decreased step length may be observed, which will increase people with PD’s changes of falling (Salarian, Russmann, Vingerhoets, Dehollaini, Blanc, Burkhard, et al 2004:1434).

People living with PD are known to walk with poor postures, which is a direct result of the loss of postural reflexes. The loss of postural reflexes results in postures becoming stooped; bent; and dropped, and may also lead to ‘dropped-head-syndrome’ (Shumway-Cook, et al 2007:242-4). The loss of postural reflexes does not only affect posture, but will decrease the centre-of-mass, which result in people living with PD struggling with multidirectional stability. Impaired multidirectional stability will affect the person’s ability to participate in multiple skills simultaneously (for example walking while carrying a cup) and it will worsen the bradykinetic symptoms (Shumway-Cook, et al 2007:243). The loss of postural reflexes are also closely linked to the loss of proprioception (Vaugoyeau, Hakam and Azulay 2011:406).

The inability of people with PD to process sensory input and proprioception may further increase poor posture and postural control and may exacerbate the motor signs associated with PD (Shumway-Cook, et al 2007:244; Vaugoyeau, et al 2011:407).

One of the motor signs that determine the accuracy of upper limb movements is ocular tracking. The ability to scan the environment while the head is still will not only assist in the speed and accuracy of upper-limb movements, but will also aid the person in the performance of ADLs (Klockgether, et al 1994:50). The decline people with PD's ability to perform ocular tracking will not only decrease upper limb function, but will also impact on the person's depth-perception-ability which will decrease the efficiency of gait (Stuart, King, Galna, Godfrey, Lord and Rochester 2015[poster]). The degree of ocular-tracking-impairment is also directly associated with the person's cognitive ability – i.e. the greater the ocular tracking impairment, the greater the degree of cognitive decline (Archibald, Hutton, Clarke, Mosimann and Burn 2013:740).

Parkinson's Disease is not only characterised by motor signs, but non-motor signs also influence function and the ability to participate in ADLs.

Non-motor signs

Non-motor impairments are among the most frequent complaints of people living with PD. The non-motor impairments associated with PD include: cognitive fallout; dementia; emotional deficits and limbic deficits (Herman, Weiss, Brozgol, Wilf-Yarkoni, Giladi and Hausdorff 2015:1115-6). Most non-motor impairments appear during the later stages of the disease but some may present prior to the onset of the motor signs. The non-motor symptoms most often reported prior to motor sign impairments consist of depression and 'rapid eye movement sleep behaviour disorder'. Although strong links exist between 'rapid eye movement sleep behaviour disorder', depression and PD, PD can only be positively diagnosed after the onset of the motor signs (Poewe 2008:16).

Dementia is one of the most common non-motor signs of PD. The impact of dementia on people living with PD affects both the person living with PD as well as his or her family's QOL. Mild cognitive impairments are also observed in people with PD and may progress to dementia as the disease progresses. The mild cognitive impairments

influence memory, processing of information and task planning (Svenningsson, Westman, Ballard and Aarsland 2012:698). The presence of dementia and cognitive impairments had a direct influence on the exclusion criteria of this study. People living with PD who suffers from dementia and moderate cognitive fallouts would not be able to understand how the intervention works, rendering this treatment method unsafe for them.

Speech difficulties associated with PD have been linked to cognitive fallout and dementia, as well as hypokinetic dysarthria caused by hypokinesia and bradykinesia (Sapir 2014:1330-1). Non-motor speech-related symptoms such as: word-finding difficulty; slow processing; confusion and sialorrhea cause people living with PD to withdraw from social settings. Patients with these symptoms tend to become isolated and reluctant to leave the house, which results in depression and anxiety when they are faced with foreign public places (Chaudhuri, Healy and Schapira 2006:235). Other non-motor symptoms that contribute to social withdrawal are nocturia and fatigue (Martinez-Martin, et al 2011:404).

Anxiety and / or depression may have a direct influence on a person's motivation, as well as their compliance with attending therapy (Pluck and Brown 2002:638-9). As PD-related depression is a result of chemical imbalances (caused by damaged neurological structures) it needs to be treated medically (Pluck, et al 2002:640). People living with PD may also develop secondary depression as a result of motor difficulties that make them reliant on family and caregivers in the performance of ADLs (Pluck, et al 2002:341). De-motivation and apathy occur in conjunction with, and separately to, depression. For this reason people living with PD needs to buy in to the concept of treatment before a home-exercise programme can effectively be put in place.

As the disease progresses people living with PD require continuous therapy as well as full-time care, as the severity of the cognitive symptoms (such as dementia, hallucinations and psychosis) as well as motor difficulties will worsen over time. Treatment for people living with motor and non-motor signs of PD is discussed in Section 2.4.

2.3.4 Activity Level Limitations in People Living with Parkinson's Disease

When movement is impaired, it is difficult to perform ADL's. The ADLs that are affected include BADLs (all grooming, self-care and eating tasks) as well as IADLs (all activities that involve the handling of apparatus or instruments) (Convinsky, Palmer, Fortinsky, Counsell, Steward, Kresivic, et al 2003:452). Losing the ability to perform BADLs and IADLs impacts on QOL, as dependence on family and caregivers increases (Convinsky, et al 2003:453). Motor and non-motor impairments can impact on a person living with PD's ability to perform IADLs and BADLs.

Bradykinesia results in difficulty with the performance of skilled, repetitive, sequential movements during the execution of ADLs (Morris 2000:580). Adamo, Martin and Brown (2007:1299) found that skilled upper-limb movements are performed less accurately in people living with PD than in unaffected individuals. This impairment results in reduced accuracy when performing all BADLs and IADLs. The authors conclude that the bradykinesia and reduced accuracy of the movement are not related to the age of the individuals, but rather to their poor hand control and impaired proprioception (Adamo, et al 2007:1299). Freezing (which is associated with akinesia) also affects patient's abilities to perform BADLs and IADLs. Freezing that occurs in the upper limb, may occur in conjunction with bradykinesia or independent thereof. When freezing presents as a motor sign of PD patients experience a sudden cessation of movement during the execution of a task (Morris 2000:580). In the upper limb, freezing may prevent patients from performing bilateral tasks, such as dressing and grooming (Morris 2000:580). When freezing occurs in conjunction with bradykinesia, patients may struggle with finer bilateral- and unilateral tasks, such as eating with a knife and fork and writing (Morris 2000:581).

Another motor sign associated with PD that impede the ability to perform ADLs is resting tremors. Initially the majority of people living with PD report symptoms of weakness of one hand in conjunction with a slight resting tremor (Helmich, Hallett, Deuschl, Toni and Bloem 2012:3207-8). As the disease progresses patients with PD tend to make significantly more mistakes than unaffected individuals during standardised upper-limb activities (Barbe, Amarell, Snijders, Florin, Quatuor, Schonau, et al 2014:333). The increase number of mistakes associated with PD-related tremors result in reduced accuracy when performing all BADLs and IADLs. .

Both the gross- and fine upper limb movements are thus affected in some way in people living with PD. Gross motor function of the upper limbs can be defined as big-body and whole-arm movement by large muscle groups, while fine motor function refers to control of the fingers, wrist and hand during specific manipulation of objects with various related hand grips (Gentier, D'Hondt, Shultz, Deforche, Augustijn, Hoorne, et al 2013:4044-7).

2.3.5 Participation Level Limitations, Personal Factors and Community Integration

Patients with PD are known to participate poorly in physical activities and ADLs, and they tend to withdraw from any social- and community activities (Throdardottir, Nilsson, Iwarsson and Haak 2013:2216). Throdardottir, et al (2013:2217-8) performed a qualitative study to determine the reasons behind the decreased participation that is observed in people living with PD. The authors found that the unpredictability of the onset and duration of the PD symptoms lead to social embarrassment and increased stress levels when these patients attempted community- and social activities (Throdardottir, et al 2013:2219). One of the most common psychological problems that occur as a result of the symptoms of PD is depression (Skorvanek, Gdovinova, Rosenberger, Saeedian, Nagyova, Groothoff, et al 2014:81-2). People living with PD become self-conscious and shy about their appearance and disability and tend to withdraw more as the disease progresses. The occurrence of depression is also closely related to patients becoming fatigued and apathetic (Skorvanek, et al 2014:85).

Motor symptoms such as difficulty with gait, poor upper-limb control resulting in difficulty performing ADL's, decreased ability to perform facial expressions, dribbling of saliva, reduced speech and inability to drive has been found to lead to worsen the depression patients with PD experience (Haahr, Kirkevold, Hall and Ostergaard 2014:338). As the disease progress and the symptoms worsen patients experience decreased motivation, which results in increased feelings of depression (Haahr, et al 2014:339-40).

Although the majority of patients experience withdrawal and decreased participation, there are facilitators to take into account that might influence a person's day-to-day as well as their therapy performance. First, it is important to acknowledge that all people are individual and although they may have the same disease they will handle it very differently. Personal drive and insight into the disease progression will play a significant role in the patients' motivation levels as well as their participation in community activities. A positive emotional state will allow patients with PD to interact and socialise and will also motivate them to want to be as active as possible (Zampieri and de Souza 2011:980-1).

Despite the personal factors that facilitates or hinders community participation, a lack of accessibility and resources play a significant role in community participation as well.

2.3.6 Environmental Factors that Influence Community Participation

One of the problems people living with PD face is withdrawal from the community. This withdrawal might be due to the patients' negative emotional state or to their inadequate accessibility to resources. Accessibility to buildings / car parks / public facilities / leisure tasks is always a large component to a person's integration into the community. Disabled parking and access to wheelchair ramps make life easier for people with disabilities but some facilities only have stairs available and no escalators or lifts; and others have no bathrooms with facilities for disabled people (Gladwell and Bendini 2004:685-7).

Access to Resources: Caregivers

Patients with access to the assistance of a well-trained professional caregiver and home resources will be more independent and have a higher QOL (Karlsson, Edberg, Jakobsson and Hallberg 2013:320-3). Social structures can also be either a facilitator or an inhibitor for people living with PD. As the disease progresses, patients who live alone find it more difficult to mobilise and basic self-care tasks take longer (Habermann and Davis 2005:50). The increased time for basic tasks makes these tasks daunting and leads to more physical and emotional exhaustion and more withdrawal from the community. If, in contrast, there is a healthy family structure and friend support it is easier to go out and far less strenuous, as others help lessen the physical burden placed on the person living with PD. Well trained caregivers can also make an immense difference as they can help with task preparation, execution and time management (Habermann, et al 2005:51).

Unfortunately, it is not always easy for patients to get a caregiver or family support as a result of the variety of cultures and beliefs in the South African context (Schatz 2007:1390). Some of the cultural beliefs in South Africa do not condone hiring a professional caregiver to look after their elders (Schatz 2007:1391-2). The use of a family member rather than a trained caregiver may be a good- or a bad arrangement, depending on the values, attitudes and beliefs of the selected family member (Schatz 2007:1392). In some cases, the family and friends of a disabled person may feel ashamed of the disability and the family may forbid the person suffering from the disability to leave the house or interact with strangers (Schatz 2007:1398). A distrust of modern medicine and medical interventions also exist in some cultures, which may hinder the health of the person with the disability (Schatz 2007:1399). Luckily, not all beliefs or cultures are negative. Most cultures treat their disabled members as equals and even assist them by making facilities more accessible. Most beliefs also support equality and assist people living with PD to reintegrate into the community (Mji, Chappell, Statham, Mlenzana, Goliath, DeWet, et al 2013:7).

Access to Resources: Assistive Devices

The use of assistive devices at home and in the community also aid in the QOL of people with PD. A walker or rollator can enable longer independent ambulation and will enable people living with PD to live longer without the aid of a full-time caregiver (Bryant, Rintala, Graham, Hou and Protas 2014:1943). Once more severely debilitating signs and symptoms become evident; people living with PD may require more specialised assistive devices. Transfer boards can help assist caregivers and family members during transfers between the bed and wheelchair; wheelchair and car and wheelchair and commode (Constantinescu, Leonard, Deeley and Kurlan 2007:133). A commode may also be acquired to assist with bathing and toileting as people living with PD become wheelchair- or bed bound. If the disability becomes this severe the correct wheelchair and mattress can also aid in QOL and prevent further secondary complications (such as pressure sores and deep vein thrombosis) (Constantinescu, et al 2007:136).

Family support: Impact of Parkinson's Disease on Family and Caregivers

After a loved one has been diagnosed with PD the family structure may change drastically. The role between carer and caregiver may now be reversed. The relationship between parent and child may also be reversed as the child might now be the primary caregiver and such a situation might result in severe stress, for both parties (Bolland, Guilfoyle and Bucks 2016:172-3). Often after the family structure has been changed the assistance of a professional psychologist may be required to aid the transition between life roles (Olsson, Claren, Alvariza, Arestedt and Hagell 2016:582). The family may now be required to assist with ADLs, house hold-tasks and communication. In this way people living with PD lose their ability to perform BADLs and IADLs and they become more dependent on their caregivers (Olsson, et al 2016:583).

People living with PD may also suffer from cognitive impairments that make them unfit to manage their finances and estate business (Martin, Triebel, Kennedy, Nicholas, Watts, Stover, et al 2013:987). The burden of financial management will move to a family member who will be given the power of attorney (Martin, et al 2013:988).

Parkinson's disease also has a severe financial impact on the patient and the family. The financial impact of PD has been investigated in the United Kingdom and the investigation found that between €9857 and €16155 per year is needed for medication, hospitalisation and direct cost of care (Fineberg, Haddad, Carpenter, Gannon, Sharpe, Young, et al 2013:763-4).

Home Environment

The motor and non-motor symptoms experienced by people living with PD have a great influence on the patients' home environments. As the typical PD gait pattern consists of shuffling gait and freezing the house needs to be adjusted to minimise falls and the risk of falling. Small changes such as no loose rugs and the presence of visual cuing lines in doorways can help people living with PD to mobilise independently at home (Suteerawattananon, Morris, Etnyre, Jankovic and Protas 2004:67-8). Kitchens must also be adjusted as people living with PD have poor upper-limb strength and find it difficult to reach top shelves or lift heavy kitchen equipment, such as blenders and slow cookers (Young and Delwaide 2013:152). Negotiating the bathroom is also a challenge. People living with PD struggle to get in and out of baths as they require upper limb strength to push up and lower limb strength to maintain balance. Therefore it may be much easier to install a shower chair and a rail to enable them to shower independently (Benge and Balsis 2016:90-2).

The home needs to be adjusted to enable independence and improve the QOL of people living with PD. A safe home environment will help people living with PD to build their confidence and decrease the depression associated with feeling helpless and dependent on others (Niewboer, et al 2007:135). The home environment also plays an important role with regard to the home exercise programme (Niewboer, et al 2007:135). If people feel safe and comfortable they may be more compliant with balance exercises or upper-limb training in their living rooms. This kind of exercise promotes healthy living and prolongs independence in the home environment (Niewboer, et al 2007:135-6).

2.4. Interventions used to Treat Parkinson's Disease

Numerous different intervention strategies are available to treat PD. The initial intervention is normally of a medical nature, as it is the neurologist who diagnoses the condition. The numerous different treatment strategies available are: medication, surgery, physical therapy (physiotherapy), and group treatment.

2.4.1 Medical Treatment for Parkinson's Disease: Pharmaceuticals / Surgical Intervention

The newest surgical intervention implemented in the management of PD-related symptoms is deep brain stimulation (Dams, Siebert, Bornschein, Volkmann, Deuschi, Oertel, et al 2013:769). The use of deep brain stimulation has been found to improve the execution of functional upper-limb and lower-limb tasks and has great long-term carry over results (Dams, et al 2013:770). The negatives of deep brain stimulation are that the procedure is invasive, requires brain surgery, and is very expensive (Dams, et al 2013:769-70). The costs related to the deep brain stimulation procedure are not paid for by most of the medical funding systems in South Africa.

Botox is a pharmaceutical intervention that is used to manage hypertonicity (rigidity) in PD and is another example of treatment that is not funded by medical aid schemes. Although Botox-therapy is effective in the management of hypertone, the effects of the intervention are only temporary. Functional gains that patients make during rehabilitation (in conjunction with the Botox-therapy) can be carried over once the effects of the Botox wears off, if the optimal physical therapy management is used (Sheffield and Jankovic 2007:137-8).

Dopamine replacement medication is a pharmaceutical intervention that is commonly prescribed to limit bradykinesia, rigidity and tremors. Dopamine replacement medication is very effective but over time the therapeutic window becomes smaller and the toxic window enlarges. Other drug therapies currently available are: dopaminergic drugs; monoamine oxidase inhibitors; and anticholinergic drugs (Olanow, Obeso and Stocchi 2006:686-7). Physical therapy interventions in combination with medication have been found more effective than medication alone.

2.4.2 Group Therapy Intervention

Group therapy is becoming more popular as a treatment modality for people living with PD, as it is relatively inexpensive and encourages social interaction (Earhard 2009:232). The latest group-class-trend for treating PD in a more social setting is Tai-Chi classes.

A study done by Li, Harmer, Fitzgerald, Eckstrom, Stock, Galver, et al (2012:511-2) compared the effects of strength training to Tai-Chi exercise over a period of 24 weeks. The results indicate that the Tai-Chi group showed greater improvement with regard to balance maintenance and functional capacity, as the exercises included rotations and trunk control and not just peripheral limb strengthening. The long-term carry over effects of the different exercise methods were not determined (Li, et al 2012:518).

Group classes have also been implemented for people with PD. Tamir, et al (2007:71-2) developed a specific full-body exercise group that incorporated strength training and rhythmical movements done to music. The authors reported that the participants enjoyed the social interaction of the group class, but the objective tests they performed showed poor functional carry over into all ADL's and no significant improvements were noted (Tamir, et al 2007:72).

People living with PD sometimes prefer receiving individual treatment sessions as they might feel shy about their own limitations or symptoms. The most frequently provided individual therapies, from the multi professional team, are given by the physiotherapists, occupational therapists and speech and language therapists. For the purpose of this study physiotherapy treatment will be discussed in more detail. This, however, does not imply that the importance of the other therapies of the multi professional team is less important.

2.4.3 Physiotherapy Management of Parkinson's Disease

People living with PD are treated by physiotherapists with the aim of prolonging independent motor control, prolonging functional independence and improving

perceived QOL (KNGF Guidelines 2004:27). Physiotherapy intervention cannot stop or slow the progressive degeneration associated with PD and it cannot heal the damage done to the substantia nigra. The role of physiotherapy is to maximise the patients' functional abilities for as long as possible and to minimise secondary complications for people living with PD (Dean, Jones, Playford, Ben-Shlomo and Clarke 2013:188-90). Physiotherapy intervention to assist in the maintenance and optimisation of motor control and improvement of QOL has been shown to be superior when compared to no intervention or placebo intervention for people living with PD (Tomlinson, et al 2012:22-3). During the systematic review done by Tomlinson and colleagues (2012:24) improvement of gait velocity, balance, functional reach and ADL's were found in the groups of people living with PD who were attending regular physiotherapy rehabilitation sessions.

There is very little published evidence available that indicate effective management strategies to enhance carry over of gross- and fine motor function of the upper limbs for people living with PD. Treatment strategies to assist motor control of the affected upper limbs of people living with PD have all been tailored or derived from strategies that are used in conjunction with the lower limbs (Tomlinson, et al 2012:25). Physiotherapists use a wide variety of treatment strategies to treat gross- and fine movement impairments with the aim of improving BADLs and IADLs. However, a lack of long-term benefits of conventional upper limb physiotherapy management strategies has been documented in the literature (Schmitz-Hubsch, et al 2005:544-5). The treatment of gross- and fine movement impairments that is currently being used for upper-limb function provides promising insight to possible means of improving upper-limb function, but a more effective functional carry-over rehabilitation strategy has still not been determined. "Functional carry over" in this context refers to the ability of patients to take a learned blocked activity and implementing the skills into a functional task (Vercruyse, Spildooren, Heremans, Vandenbossche, Wenderoth, Swinnen, et al 2012:363).

Conventional physiotherapy treatment strategies and –protocols that are currently implemented in clinical practice include: compensation strategies, blocked practice, group classes and verbal cueing (Chaudhuri, et al 2006:241; Goodwin, et al 2008:638; Vercruyse, et al 2012:340; Bengel, et al 2016:85).

Owing to the progressive degenerative nature of PD some practitioners have adopted compensation strategies as the first choice of treatment during rehabilitation, rather than using the traditional restorative rehabilitation approaches (Piemonte, Oliveira, Miranda, Guelfi, Souza, Okamoto, et al 2015:1-2). Short-term motor improvements were noted with the use of compensatory strategies during rehabilitation, but long-term functional carry over was not observed (Piemonte, et al 2015:5). Due to the lack of long-term carry over the majority of therapists have reverted back to using restorative rehabilitation approaches (Piemonte, et al 2015:5).

Another treatment approach that is used is during the physiotherapy management of patients with PD is 'task-specific block therapy'. The basic principle underpinning this type of therapy is to break a functional task into smaller components. Each component is then practiced until the therapist is confident that the patient is able to perform that specific component. Once all the components of the task can be executed to a satisfactory level the movements are combined and a functional task is performed (Quinn, Busse and Dal Bello-Haas 2013:149-50). Although long-term functional carry-over has not been reported in the literature, the positive short-term results of the performance of functional tasks warrant the implementation of this method of rehabilitation in the management of upper-limb impairments in PD sufferers (Quinn, et al 2013:153).

Verbal cueing and imagery is another physiotherapy intervention utilised in the management of PD. The use of verbal cueing and imagery was tested to determine the effect on both upper- and lower-limb movements in people living with PD (Vercruyssen, et al 2012:634-7). The participants in the study by Vercruyssen and colleagues presented with freezing of gait and reduced upper- and lower-limb strength. The results the authors obtained indicated that verbal cueing and imagery interventions improved the frequency at which movement occurred, the amplitude of movement and the movement co-ordination patterns during the execution of ADLs. The results also revealed that there was very little carry over of the improvements observed in functional activities once the cueing was removed. The results of this study provides promising insight into possible interventions that could be used to

improve upper-limb function, but a more effective way of promoting function carry over still has to be developed (Vercruyssen, et al 2012:643-7).

2.4.4 Virtual Reality Therapy

One of the emerging rehabilitation strategies that focuses on the re-education of motor control in patients with neurological disorders is VR therapy (Golomb, McDonald, Warden, Yonkman, Saykin, Shirley, et al 2010:1). VR therapy entails the use of a visual medium, such as an animation on a screen, to allow the patient to engage with active movement in a real-life simulated environment. The patient therefore experiences the virtual environment as a real functional environment in which she/he is stimulated to perform activities (Golomb, et al 2010:2-3). By performing voluntary, active, movement in a virtual environment the potential exists that motor control can be improved in patients with neurological disorders (Rahman, Rahman and Shaheen 2011:63-4). Virtual Reality therapy makes use of a Kinect camera that is powered by both hardware and software. The camera creates both a three-dimensional image of the object as well as recognises human beings. Therefore, as the human moves the camera follows the person and creates a three-dimensional image of that movement. The created movement is then mimicked by an avatar on the screen (Wann and Mon-Williams 1996:834). When a VR system is used in rehabilitation a patient does not only have constant visual feedback of their movements, but they also need to meet certain criteria to complete the game. If the games that the patients play are correctly selected the games can focus on the movements the patients find challenging in their own homes (Riener and Harders 2012:161-70). Participating in game-play is also enjoyable and competitive which assists in keeping the patients interested to take part.

Virtual reality is thus a medium through which exercise can be administered to people with neurological disorders so that functional movements can be trained (Golomb, et al 2010:3). A VR-based study (Tarr, et al 2002:1090) carried out on people with PD showed improvement of the cognitive functioning of patients during shopping.

The researchers, however, did not measure change in the upper- and lower-limb functioning of the patients who participated in the study. The VR apparatus that was by Tarr, et al (2002:1091) was not freely available to patients at the time; therefore,

patients could access the VR apparatus only at the rehabilitation practice during a physiotherapy session.

Virtual reality therapy has been found effective when used for rehabilitation of upper limb-, lower limb- and trunk movement, as well as for improving BADLs and IADLs in patients who have sustained CVIs (Saposnik, et al 2010:1481). As VR training is more enjoyable than conventional therapy, researchers found that people with CVIs were more willing to perform multiple repetitions of functional tasks that were not always possible in a clinical environment (Laver, George, Thomas, Deutsch and Crotty 2011:20-2). Another study found that fewer compensatory strategies were used by patients during the execution of functional tasks, after receiving VR therapy (e.g. trunk movements to facilitate shoulder flexion) (Subramanian, et al 2013:20-1). This study also reported that improved feedback-strategies were used by patients and greater improvement in functional upper-limb tasks during VR training was observed when VR therapy was compared to conventional therapy (Subramanian, et al 2013:22-3). In a study by Henderson, et al (2007:59-60) the researchers reported that people living with CVIs who received VR therapy showed marked improvement in upper-limb function with regard to functional carryover in BADLs and IADLs when compared with a control group that received conventional physiotherapy.

Freely available VR apparatuses, such as the X-Box Kinect[®] and Nintendo Wii[®], have been found effective when used as treatment modalities during the rehabilitation of upper-limb function people living with TBI (Merians, Jack, Boian, Tremaine, Burdea, Adamovich, et al 2002:911). Patients with TBIs who were treated with VR therapy also showed marked improvement in the performance of upper-limb specific task speeds, as well as better accuracy and efficiency during the execution of functional tasks (Mumford, Duckworth, Thomas, Shum, Williams and Wilson 2011:172). A study investigating the carry-over effect of VR training in chronic TBI patients found that functional progress stops when therapy is terminated, but the patients displayed no functional regression after the VR training was stopped (Albiol-Perez, Gil-Gomez, Llorens, Alcaniz and Font 2014:395-8).

Therefore, the authors advise that patients acquire their own VR device so that they can participate in a VR-based home exercise regime (Albiol-Perez, et al 2014:398).

The implementation of VR therapy as a home exercise program has also been studied within the MS community (Thomas, Fazakarley, Thomas, Brenton, Collyer, Perring, et al 2014:6-7). Clinical and statistical significant improvement in upper-limb function was reported when VR-based home exercise programmes were compared to standard home exercise programs (Thomas, et al 2014:7). The benefits of VR training for patients with MS also included improved upper-limb function during the therapy session as well as improvement of function in-between sessions. This improvement indicates a significant carry over effect between therapy sessions for functional upper-limb tasks (Basteris, De Luca, Sanguineti, Solaro, Mueller, Carpinella, et al 2011:4-5).

Rovetta, et al (1998:184) were the first to implement VR therapy for people living with PD. Owing to the limited availability of VR therapy resources when the study was implemented, the intervention was limited to fine motor activities in the hand (only single finger movements in the hand). The participants showed improvement only in finger flexion and -extension. A VR-based study that was performed when the technology was more available (Tarr, et al 2002:1089-90) showed improvement of the cognitive functioning of people living with PD during shopping. The researchers did not report any change in the patients' function, as it was not part of the research design. The VR apparatus that was used in this study was not freely available at the time; therefore, patients could only access the VR apparatus at the rehabilitation practice during a physiotherapy session.

Similar VR apparatus (that was not freely available) was used in a study by Lee, Ku, Cho, Hahn, Kim, Lee, et al (2003:386) on people living with PD. The authors developed a VR game with the aim of improving function during ADLs. The results indicated improved fine- and gross upper-limb function, but as a result of the small sample size of this study, statistically significant improvement could not be determined (Lee, et al 2003:388).

Freely available VR technology (such as the Nintendo Wii[®]) has only recently been implemented as an intervention method for people living with PD. During a study in 2012, the Nintendo Wii[®] was used to rehabilitate motor function and balance (Pompeu, dos Santos, de Silva, Lobo, Oliveria, Zomignani, et al 2012:200). The results obtained during the study indicated clinically significant improvement in the patients' ability to maintain standing balance while performing ADLs (such as grooming) (Pompeu, et al 2012:202). The effect of VR administered through the X-Box Kinect[®] in the treatment of upper-limb function in people with PD, has not been reported in the literature.

2.4.5 Ocular tracking

Ocular tracking is the ability to maintain the head in a still position, while the eyes are scanning the environment. The ability of a patient to perform ocular tracking is closely linked to the ability of the patient to perform upper-limb function (Rand and Stelmach 2010:200-2). Upper-limb activities that are performed during the implementation of VR therapy will therefore naturally also include ocular movement. Furthermore, the researcher hypothesises that the ocular tracking that is required for performing the VR-tasks will help with the improvement of upper-limb function.

Upper-limb movements, and specifically hand function, guide ocular movement. Klockgether, et al (1994:54-6) found that ocular tracking assists in upper-limb movement and increases the accuracy and speed at which functional upper-limb tasks are performed. One of the limitations of the study was that improvements in the patients' ability to perform ocular tracking were only noticed after the intervention. The improvements in ocular tracking that were observed were not accurately documented, as the main objective of the study was to measure improvement in upper-limb function and not ocular tracking. The correct use of objective measurement is therefore critical in determining whether the chosen physiotherapy intervention has been successful.

2.5. Outcome measures

Outcome measures are used in clinical practice to objectively determine the baseline status of a patient, and to establish whether intervention affected / influenced this baseline status (Salter, Campbell, Richardson, Mehta, Jutai, Zettler, et al 2013: 4). When outcome measures are used in the management of patients with neurological conditions, they are selected and implemented based on the aims of the therapy set by the physiotherapist – for example: If the aim of rehabilitation is to improve upper-limb function, an outcome measure on the ‘impairment’-level of the ICF will be selected. However, if the aim of the intervention is to improve function an outcome measure to determine the intervention’s effect on ADLs (‘activity’-level outcome measure) will be selected (Salter, et al 2013:5)

In order to guide therapists to select the most appropriate outcome measures for the management of PD patients (based on the ICF-framework) the Parkinson Edge Task Force was established (<http://www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations/parkinson-disease>). The task force evaluated all the outcome measures that were created for use in PD patients and classified the various outcome measures according to the ICF. The task force further made recommendations, based on recommendation categories (Table 2.1), on whether the outcome measure is suitable for clinical use, educational purposes and / or research use (<http://www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations/parkinson-disease>).

Table 2.1 Recommendation Categories for PD Outcome Measures

Rank Allocation	Recommendation	Description
4	Highly recommended	<ul style="list-style-type: none"> • Excellent psychometric in target population (valid and reliable with available data to guide interpretation), AND • Excellent clinical utility (e.g. administration is ≤ 20 minutes, requires equipment typically found in the clinic, no copyright payment required, easy to score).
3	Recommended	<ul style="list-style-type: none"> • Good psychometrics (may lack information about reliability, validity or available data to guide interpretation) in target population; AND • Good clinical utility (e.g. administration / scoring > 20 minutes, may require additional equipment to purchase or construct).
2	Reasonable to use, but limited to specific target groups	<ul style="list-style-type: none"> • Good or excellent psychometric data demonstrated in at least one population but insufficient study in target population to support a stronger recommendation (does not have any negative psychometric data); OR • Good clinical utility (e.g. administration / scoring > 20 minutes, may require additional equipment to purchase or construct).
1	Not recommended	<ul style="list-style-type: none"> • Poor psychometrics (inadequate reliability or validity) OR • Limited clinical utility (extensive testing time, unusual or expensive equipment, ongoing costs to administer, etc.).

The main reasons for using outcome measures in this study were to ensure that the results that were obtained during the data collection were accurately measured and that bias was eliminated. The use of outcome measures that are objective, valid and reliable also ensures optimal quality of the data. The researcher selected outcome measures based on the following criteria:

- The outcome measures had to align to the aims and objectives of the study, which were: to determine the effect of VR therapy on gross- and fine upper-limb motor control before, during and after the intervention; to determine the effect of VR therapy on the quality of functional upper limb movement before, during and after the intervention; and to determine the effect of VR therapy on ocular tracking before, during and after the intervention.
- The outcome measures had to align with the ICF framework, i.e. outcome measures were selected on the 'impairment', 'activity', and 'participation' levels of the ICF.
- The outcome measures had to receive a recommendation by the Parkinson Edge Task Force of a three or four.

Once outcome measures were selected according to the aforementioned criteria, each objective measure was appraised for suitability for inclusion in this study, based on the framework of Norman and Heroux (2013:5-6). The appraisal of the outcome measures can be seen in Tables 2.2, 2.3 and 2.4.

Table 2.2 Outcome Measures for Fine Upper-limb Motor Control

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
9 Hole Peg Test	3	<ul style="list-style-type: none"> • Easy to administer • Takes less than 5 minutes to complete 	<ul style="list-style-type: none"> • Requires specific pegs and a pegboard 	<ul style="list-style-type: none"> • Evaluates visuomotor control, grip, grasp and release • Suitable for fine hand movement assessment 	<ul style="list-style-type: none"> • Good – measures performance in time (with a stopwatch) 	<ul style="list-style-type: none"> • Well known test, easy to understand and no training required. • Valid and reliable • Tested on the PD population • Normative results 	Yes*
Functional Reach Test	3	<ul style="list-style-type: none"> • Easy to administer • Takes less than 5 minutes to complete • Assesses patient in sitting and standing 	<ul style="list-style-type: none"> • Limited testing – true function and fine hand movement not assessed 	<ul style="list-style-type: none"> • Evaluates ability to reach forward • Measures trunk control to a certain extent 	<ul style="list-style-type: none"> • Good – measures performance in centimeters (measuring tape) 	<ul style="list-style-type: none"> • Well known test, easy to understand and no training required. • Valid and reliable • Tested on the PD population • Normative results 	No – fine hand movement not assessed with the test

Table 2.2 (continued) Outcome Measures for Fine Upper-limb Motor Control

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
Pardue Pegboard Test	3	<ul style="list-style-type: none"> • Easy to administer • Takes less than 5 minutes to complete 	<ul style="list-style-type: none"> • Limited testing – originally developed for manual labor workers • Copyright licence for use required 	<ul style="list-style-type: none"> • Evaluates visuomotor control, grip, grasp and release • Suitable for fine hand movement assessment 	<ul style="list-style-type: none"> • Moderate – timed (with a stopwatch) but mathematical calculation required for interpretation 	<ul style="list-style-type: none"> • Not a well known test, but easy to understand • Valid and reliable • Tested on the PD population • Normative results • Copyright licence required 	No – too similar to the 9 Hole Peg test with too many limitations
Push-release Test	3	<ul style="list-style-type: none"> • Easy to administer • Takes less than 10 minutes to complete 	<ul style="list-style-type: none"> • Although patients use their hands during the test, upper-limb strength is tested and not fine hand movement 	<ul style="list-style-type: none"> • Main focus is upper limb strength, then balance – fine hand movements not objectively measured 	<ul style="list-style-type: none"> • Moderate – lickert scale used but mathematical calculation required for interpretation 	<ul style="list-style-type: none"> • Not a well known test, but easy to understand • Valid and reliable • Does not assess fine hand movement 	No – fine hand movement not assessed with the test

*The 9HPT was selected as it is the most suitable outcome measure to assess fine hand function.

Table 2.3 Outcome Measures for Gross Upper-limb Motor Control and Function

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
Continuous Scale Functional Performance	3	<ul style="list-style-type: none"> Comprehensive test of function Items on the scale is performed fully and not just demonstrated 	<ul style="list-style-type: none"> 10/16 items assess lower-limb function 60 minutes to complete Requires a lot of equipment Not freely available 	<ul style="list-style-type: none"> Measures activity and participation level outcomes Majority of the items assess lower-limb function 	<ul style="list-style-type: none"> Low – results from the test have to be processed with data reduction software 	<ul style="list-style-type: none"> Comprehensive tool that is easy to administer Very costly and data analysis hindered if software is not purchased 	No – test is too lengthy, costly and requires too much additional equipment
Movement Disorder Society Sponsored Unified Parkinson;s Disease Rating Scale	4	<ul style="list-style-type: none"> Comprehensive test Freely available Moderately easy to assess 	<ul style="list-style-type: none"> Main function of tool is to assess quality of life 30 minutes to complete 	<ul style="list-style-type: none"> Mainly used to assess quality of life for people with mild to severe symptoms as a result of PD 	<ul style="list-style-type: none"> Good – measures performance with an ordinal scale 	<ul style="list-style-type: none"> Easy to administer Easily accessible using freely available equipment Time consuming Test incorporates only one ICF aspect 	No – test is too lengthy and does not assess gross upper-limb motor control and function, per se.

Table 2.3 (continued) Outcome Measures for Gross Upper-limb Motor Control and Function

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
Parkinson's Disease Questionnaire - 39	4	<ul style="list-style-type: none"> • Easy to administer • Freely available 	<ul style="list-style-type: none"> • 20 minutes to complete • Only 6/39 items evaluate the perception of function 	<ul style="list-style-type: none"> • Main function is to gain a holistic overview of the patient's perception of the effect of PD 	<ul style="list-style-type: none"> • Low – self reported questionnaire 	<ul style="list-style-type: none"> • Easy to administer • Not too time consuming • Too many items not related to upper-limb function 	No – too many items of the questionnaire not applicable to function
Physical Performance Test	3	<ul style="list-style-type: none"> • Easy to administer • Freely available • Uses freely available items • 5 to 10 minutes to complete 	<ul style="list-style-type: none"> • Only evaluates activities – not the application of the activity into daily life • Subjective reporting of results 	<ul style="list-style-type: none"> • Main function is to assess the 'activity'-level ICF domain in patients with PD who present with dementia / severe 	<ul style="list-style-type: none"> • Low to moderate – an investigator-reported nominal scale 	<ul style="list-style-type: none"> • Easy to administer • Time efficient • Target population not included in validity and reliability testing • Subjective reporting of results 	No – only 'activity' level outcomes tested; test too subjective for scientific use; not suitable for study population

				cognitive fallouts			
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Table 2.3 (continued) Outcome Measures for Gross Upper-limb Motor Control and Function

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
Test D'evaluation Des Memberes Superieurs De Personnes Agees (TEMPA)	Not rated	<ul style="list-style-type: none"> • Freely and easily accessible • Easy to understand - evaluator only needs to read through the manual prior to the test • Equipment used in the test is freely available 	<ul style="list-style-type: none"> • 10-20 minutes to complete 	<ul style="list-style-type: none"> • Timed test to determine gross- and fine upper-limb movement; tests activities of daily living and application of these activities (i.e. participation) 	<ul style="list-style-type: none"> • Good – measures performance in time (with a stopwatch) 	<ul style="list-style-type: none"> • Easy to administer • Not too time consuming • Easily accessible using freely available equipment • Test incorporates all three ICF aspects 	Yes* - although not rated by the task team, it is the most suitable test to assess upper-limb function

*Although the TEMPA is not rated by the Parkinson Edge task force, it is the most suitable tool to test gross upper-limb function, 'activity'- and 'participation' level outcomes in patients with PD. The test was also used in the collaborative study by the University of Brazilia.

The outcome measures available for testing ocular tracking has not been appraised by the Parkinson Edge task force. Therefore, the outcome measures that have been used in the assessment of patients with other neurological disorders were evaluated for inclusion in this study. The appraisal of the outcome measures can be seen in Table 2.4.

Table 2.4 Outcome Measures for Ocular Tracking

Outcome Measure	Parkinson Edge Task Force Score	Constructs (Positive)	Burden (Negative)	Purpose (Suitability)	Measurement (Objectivity)	Interpretation	Used in this study / not
King Devick Test	Not rated	<ul style="list-style-type: none"> • Easy to administer • Easily accessible • Developed to measure ocular tracking 	<ul style="list-style-type: none"> • Not specifically designed for PD 	<ul style="list-style-type: none"> • Main purpose – to measure ocular tracking in patients with neurological disorders 	<ul style="list-style-type: none"> • Good – measures performance in time (with a stopwatch) 	<ul style="list-style-type: none"> • Easy to administer • Not too time consuming • Measures ocular tracking 	Yes* - it is the most suitable test to assess ocular tracking
Motor Free Visual Perception Test	Not rated	<ul style="list-style-type: none"> • Comprehensive visual test • Easy to administer 	<ul style="list-style-type: none"> • Not specifically designed for PD • Measures visual perception 	<ul style="list-style-type: none"> • Main purpose is to measure vision and visual perceptual 	<ul style="list-style-type: none"> • Low to Moderate – an investigator-reported nominal scale 	<ul style="list-style-type: none"> • Focus of test on vision and visual perception – ocular tracking not measured 	No – test does not specifically measure ocular tracking
Star Cancellation Test	Not rated	<ul style="list-style-type: none"> • Easy to administer • Easily accessible 	<ul style="list-style-type: none"> • Not specifically designed for patients with PD 	<ul style="list-style-type: none"> • Main aim is to determine the severity of hemispatial neglect 	<ul style="list-style-type: none"> • Good – measures performance in time (with a stopwatch) 	<ul style="list-style-type: none"> • Focus of test on hemispatial neglect rather than on ocular tracking 	No – test does not specifically measure ocular tracking

*The King Devick test was selected as it is reliable, valid and focuses on ocular tracking not visual perception.

2.6. Summary

The literature review described the current rehabilitation techniques used for people living with PD. The literature review revealed that the use of VR therapy for people living with PD has been effective. However, the research that has been published was limited to finger movement retraining and cognitive tasks only. The VR therapy modalities that were implemented in the published research, for people with PD, are limited in terms of their availability to patients outside of the physiotherapy treatment sessions. The lack of research on easily accessible, inexpensive VR therapy for people living with PD was one of the main reasons why this study was conducted. By giving people living with PD an inexpensive, easy-to-use home based supplementary treatment regime patients could potentially reduce the number of out-patient therapy appointments and maintain their independence for longer. The literature review also focused on the gaps seen in the current research with regard to physiotherapy treatment for people living with PD. Chapter Three describes the methodology used for the study.

CHAPTER 3

METHODOLOGY

3.1 Introduction

In Chapter 1, the background to, rationale for, and aims and objectives of this study were presented. Chapter 2 reviewed the literature relating to PD with specific reference to factors such as the use of virtual reality as an intervention for the rehabilitation of the signs and symptoms related to PD. A number of objective measurement instruments for measuring the variables of interest in this study were also identified and selected for use in this study.

In this chapter, the research methodology is set out in terms of the study design, the study setting and the procedure used for participant selection. The chapter also describes how the randomised controlled trial (RCT) procedure was implemented in line with the Consolidated Standards of Reporting Trials (CONSORT) Statement and the completed CONSORT checklist is attached to this document (Appendix A). The pilot study that was executed prior to the onset of the trial is discussed in this chapter, as well as the data analysis that was applied to the pilot study results and the collected data from the RCT. The chapter ends with a description of the ethical considerations that were implemented before and during the execution of this study and a brief summary of the chapter.

3.2 Study Design and Randomisation

The research design that was implemented during the execution of this study was a single blind RCT. By using an RCT the researcher was able to determine whether the changes that were observed were as a result of the intervention or not (Ahn and Ahn 2010:277). The conduction of RCTs are becoming increasingly important, as a well-designed RCT can provide the evidence required to optimise clinical practice (Stanley 2007:1164).

The participants in this study were randomly allocated to either the control- or experimental treatment groups by using the concealed opaque envelope method. The allocation of participants to the groups was done by the secretary of the rehabilitation centre using the concealed-envelope allocation strategy to ensure that all participants had an equal chance of being allocated to the experimental- and the control groups after they had met the inclusion and exclusion criteria (see Section 3.4).

The concealed-envelope allocation strategy entailed using 22 opaque envelopes with one of two different colour papers on the inside. Eleven envelopes contained red papers and 11 envelopes contained green papers. Once the envelopes were sealed, the researcher shuffled them and handed them to the receptionist. Participants were handed an opaque sealed envelope when they arrived and they were asked to write their name on it prior to opening it. The participant was then allowed to open the envelope and see what colour he or she received. The 11 participants who drew an envelope with a red piece of paper were in the group that received treatment with the VR apparatus and pre-selected exercises that focused on rehabilitation of the upper limb.

The 11 participants who drew an envelope with a green piece of paper were in the group that received conventional physiotherapy and they received predetermined conventional physiotherapy treatment for the upper limb.

To ensure optimal quality during the execution of the study design the researcher knew the allocation groups, but the assessor (who conducted the three assessments) was blind to the group allocations. The assessor was also blinded with regard to the intervention the participants received.

3.3 Research Setting

The study was conducted at the “Rehab Matters” Rehabilitation Centre in Bryanston, North of Johannesburg. “Rehab Matters” is an out-patient rehabilitation facility that provides care for people living with hemiplegia, TBI, MS, PD, limb amputations, cancer, vestibular problems and motor neuron diseases.

Permission to use the “Rehab Matters” rehabilitation centre as the setting for this study, was given by the owners of “Rehab Matters” (Appendix B). Patients at the rehabilitation centre received physiotherapy two to three times per week, for 45 minutes each. Occupational therapy, speech therapy, audiology services, dietetic, psychology and sexology counselling were available to patients at the centre, should the patients have required these services or counselling. The consultation services of a rehabilitation doctor, a neurologist and neurosurgeon were also available to the patients.

There are multiple treatment areas in the “Rehab Matters” facility. The gymnasium that was used for this study has a projector and screen that the X-Box[®] games were projected onto. The gymnasium also has two plinths where the participant could lie down if he / she experienced increased or decreased heart rate or increased or decreased blood pressure. The gymnasium has a large open floor area where a wooden chair with a backrest and no arm rests was positioned. Participants in the experimental group sat on this chair for the duration of treatment with the VR apparatus. Participants allocated to the control group (who received conventional therapy) were treated in the same gymnasium and made use of the plinths, chairs and a table.

3.4 Study Population

The target population for this study was people living with PD within the Bryanston area who received rehabilitation at “Rehab Matters” Rehabilitation Practice. Participants were asked to participate voluntarily in the study. Another sampling source was members of the South African Society for Parkinson’s Disease living in the Bryanston area. The PD support group was also approached for participants, in order to ensure a large sampling frame. Participants who met the inclusion criteria were recruited. Participants who did not meet the inclusion criteria were not enrolled in the study.

Inclusion criteria

- Participants had to have a confirmed diagnosis of Parkinson's Disease from a medical specialist. This was to allow the results to be a true reflection of the impact of the various interventions.
- Participants of all races, languages, and both genders who were above the age of 18 were recruited. Allowing all different genders, languages and races enabled a true representation of the PD population and helped eliminate bias.

Exclusion criteria

- Participants who suffered from co-morbid diseases such as PD-related dementia, uncontrolled hypertension and cardiovascular conditions, pulmonary complications, diabetes mellitus and photosensitive epilepsy as identified by the demographic questionnaire. This criteria excluded people with dementia as they would not be able to take part safely in the VR therapy protocol (Buss 2009:13). Dementia sufferers are able to partake in simplified VR therapy intervention but it has to be tailored to each individual's cognitive abilities and is less intense than the protocol used in this study (Buss 2009:13). As a safety precaution pulmonary conditions and uncontrolled cardiovascular conditions were excluded as both interventions include endurance work, which would be unsafe for people with uncontrolled medical conditions. People with photosensitive epilepsy would not be able to partake in VR therapy as the system has flashing lights that may cause epileptic attacks.
- Participants who scored less than 24/30 on the Mini Mental State Examination (MMSE). The MMSE indicates the cognitive capabilities of people living with PD and if the score is below 24/30 participants would not be able to understand the VR therapy protocol.
- Participants who did not provide written informed consent to participate in the study.

3.4.1 Sample Size

The sample size for the study was calculated by a biostatistician. The statistician took into account the statistics of the prevalence of PD in South Africa as well as the population figures for the area in which the study took place. The statistician then calculated that a sample size of 22 participants would be adequate. The 9HPT was the main objective measure tested in the study and a sample size of 11 participants in each group was adequate to determine whether statistically significant change occurred between patients in the two groups.

The number of participants used was in line with the number of participants used in other PD studies. Goodwin, Richards, Taylor and Campbell (2008:633) conducted a systematic review on PD patients and these authors found that most of the RCTs that had been performed shown average sample sizes between 11 to 56 participants, with a mean sample size of 25.6. Previous RCTs conducted on patients with PD in South Africa also consisted of fairly small sample groups. A study done in the Western Cape had only 20 participants (Uys, 2008:22), as the researcher had difficulty recruiting more people living with PD.

3.5 Participant Recruitment Procedure

3.5.1 Briefing and Informed Consent

Participant recruitment was done at the rehabilitation centre where the study was conducted and PD support groups in the Gauteng region. The 22 participants who were willing to take part in the study were briefed on the details as well as on the potential risks of the study by the principal researcher. Participants received a participant information leaflet (Appendix C) that they had to read through and sign to the effect that they understood the details of the study prior to taking part in it. No uncertainties arose from the participants after having read the information leaflet and there were no additional questions. Participants found the leaflet to be self-explanatory and easy to understand. The participants were then asked to sign an

informed consent form, agreeing to take part in the study. The briefing and informed consent procedure took five minutes to complete.

3.5.2 Screening

After providing informed consent and before randomisation, the participants were screened to ensure eligibility for participation in the study. The screening process consisted of the participants completing a demographic questionnaire (Appendix D), and a MMSE questionnaire (Appendix E). The demographic questionnaire included questions to help determine if the participants conformed to the inclusion and exclusion criteria. The demographic questionnaire took an average of four minutes to complete and all the participants reported it easy to complete the questionnaire independently.

All 22 participants also completed the MMSE questionnaire. The MMSE questionnaire was conducted by the principal researcher with the aim of assessing the participants' cognitive function. If a participant scored under 24/30, they were excluded from the study. The MMSE questionnaire was easy to understand for the participants and the researcher found that it was easy to administer as well. The MMSE questionnaire took an average of five minutes to complete.

Figure 3.1 illustrates the participant recruitment procedure, randomisation and the follow up procedure (<http://www.consort-statement.org>; Egger, Juni and Bartlett 2001:1998).

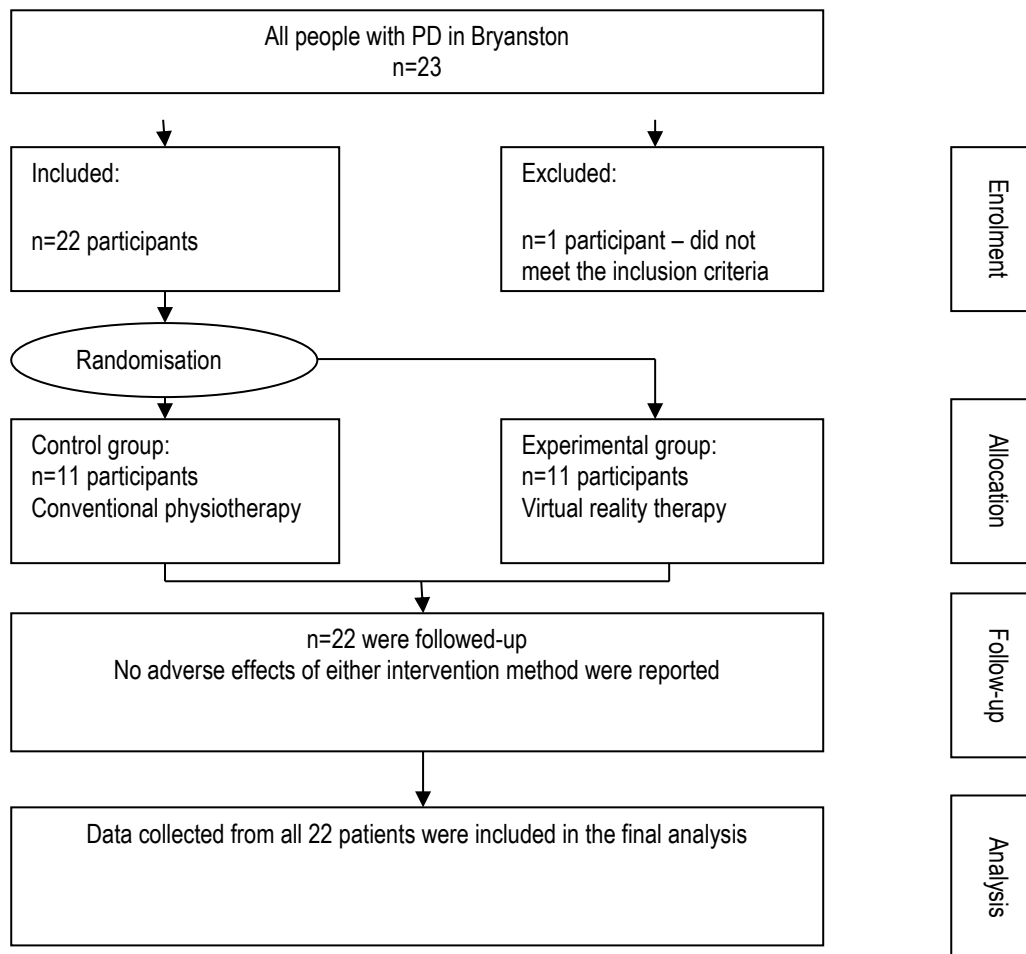


Figure 3.1 Flow Chart of Randomisation- and Follow -up Procedure based on the CONSORT-model (<http://www.consort-statement.org> & Egger et al., 2001).

3.6 Data Collection Procedure

3.6.1 Assessor Training

A qualified physiotherapist, registered with the Health Professions Council of South Africa (HPCSA), and working in the field of neurorehabilitation was used as an independent blinded assessor. The blinded assessor was trained to perform and record all outcomes measures that were used in the trial. The assessor did not take part in the intervention and was blind to which intervention each participant received. The assessment of each participant was done at a venue separate from the one used to perform the interventions.

Assessor training was done prior to the onset of the study and the assessments were at three intervals: prior to the first intervention session; after six treatments; and after 12 treatments. To eliminate bias during the assessments the principal researcher did not conduct or witness any of the assessment sessions.

3.6.2 Outcome Measures used during the Assessments

The following outcomes measures were used by the blinded assessor during all three of the assessments: 9HPT, TEMPA and the King Devick Test. The assessment took approximately 20 minutes to complete, per participant. All the data that was collected during the assessments was captured on the data-capture sheets (Appendix F) and are stored at the University of Pretoria. The data was kept confidential during the data capturing process and will be kept confidential and stored for 15 years at the University of Pretoria (Appendix G).

The 9-hole Peg Test (9HPT)

The 9HPT was used to assess the fine motor control of the participants. The test consists of a nine-by-nine-inch board with space for nine pegs to be placed into the holes. All the pegs are equal in size and have to be accurately placed into the holes in as little time as possible. The 9HPT took approximately five minutes to complete (data capture sheet - Appendix F1). The assessor reported that it was easy to administer the test. Participants were able to understand the test without difficulty. The test proved to be effective in measuring in-hand manipulation and fine IADLs

Test d'Evaluation des Membres Superieurs De Personnes Agees (TEMPA)

The TEMPA evaluated the motor function during BADL-tasks of the participants. The TEMPA tasks included basic activities such as: pouring water, opening a jar, putting on a scarf, working with a key, using coins, moving small objects and putting a stamp on a letter. Quantitatively all tasks were timed and recorded on the data capture sheets (Appendix F2). The test took approximately ten minutes to complete.

Although the TEMPA's reliability has not been tested on the South African population, the participants reported no difficulties understanding the tasks or performing them. The assessor reported that the participants were familiar with all the tasks and the participants said that they do most of the tasks at home.

King Devick Test

The King Devick Test was the assessment tool used for objectively measuring ocular tracking and scanning. The test entails the rapid reading of numbers that are arranged in specific patterns on a piece of A4 paper. The participants had to read the numbers from the paper in the correct sequence in as little time as possible. The assessor recorded the number of mistakes as well as the time it took to complete the test (Appendix F3). The test took on average four minutes to complete. The assessor reported that the test instructions were clear and the participants found the test easy to complete.

3.6.3 Participant Safety during the Intervention

Automatic Sphygmomanometer

In order to ensure the participants' safety during the implementation of the intervention the BeurerOberarm-Blutdruckcomputer model BM 10[©] was used to measure blood-pressure (BP) and heart rate. The automatic sphygmomanometer was tested during all the treatment sessions of the pilot study. The cuff was placed over the non-dominant biceps muscle and the BP and heart rate was measured every ten minutes. The researcher did the five measurements and participants found that the cuff was neither a distraction nor an obstruction during the tasks. The sphygmomanometer was then used during the intervention of both control- and experimental group participants.

Other precautions

Although none of the participants experienced any medical problems during the pilot study, safety precautions were put in place to ensure that participants could be managed swiftly if adverse events occurred. A plinth was available for resting if a participant suffered from fatigue, exhaustion or elevated BP. Furthermore, a medical doctor was on standby to assist if the vital signs of the participants did not return to normal within ten minutes of resting. The doctor was situated at an out-patient facility next to “Rehab Matters” Rehabilitation Centre.

3.6.4 Intervention

The researcher conducted the conventional physiotherapy (control)-group intervention as well as the VR therapy (experimental)-group intervention. Participants of the VR therapy group (experimental group) were in a seated position for the duration of the intervention and the treatment session lasted 45 minutes. Participants in the conventional physiotherapy group (control group) were in the seated, prone and supine positions for the intervention and the duration of the treatment session was also 45 minutes.

Virtual reality therapy (experimental) group intervention

The X-box Kinect[®] VR apparatus was used as the treatment instrument for the VR therapy (experimental) group during the study. Each participant completed 12 treatment sessions of 45 minutes, twice a week. The first, sixth and last sessions were longer, as all outcome measures were taken during the session and took 60 minutes to complete. Although 60 minutes appears to be very lengthy, the participants found it was easy to cope with and reported that they did not feel too fatigued after the session, as they were allowed to rest in between tests and exercises. The entire intervention was done in a seated position with the sphygmomanometer attached to the non-dominant arm. The VR games were projected onto a screen in order for participants to see the picture easily. One of the participants reported that he found the picture clear even with eye sight of -2.5 and -2.0.



The chair was well aligned with the VR-sensor and the sensors were calibrated to suit each participant. The researcher used a variety of pre-selected games to address both gross- and fine upper-limb movements. The games invariably included scanning eye movements.

The games that were played during the treatment were selected as they included all the aspects of movement needed for participants to participate in ADLs. The games addressed gross- and fine upper-limb movements as well as ocular tracking.

Prior to starting the intervention the researcher demonstrated one game to allow the participants to see how the avatar moved and what was required from them. After the demonstration the participants felt they knew what to do and how they should move to enable the avatar to perform the task during gross- and fine upper-limb movements. The first game was used to allow the participants to practise and get familiar with the movement required to use the avatar effectively.

During the game for hand function, the participants were asked to use only one hand at a time to manipulate the remote control. The game was repeated twice (once with each hand) so that both hands could manipulate the control. Participants found the remote control light to pick up and the buttons were easy to manipulate. Visual tracking naturally occurred during all of the above mentioned games. For the first game all participants played Kinect Sport bowling: beginner level. This was the easiest game and allowed the participants to get familiar with the X-Box Kinect[®] and to prepare for the more advanced games. Refer to Table 3.1 for the games that were played over the 12 sessions and what movements were targeted during each task.

Table 3.1 VR Games and Targeted Movements for the Experimental Group

X-Box game name	Specific games	Gross upper limb movement	Fine upper limb movement	Hand function	Ocular tracking
Kinetic Olympics 	Bowling	X	X		X
	Track and field	X	X		X
	Tennis and Baseball	X	X		X
Kinetic Adventures 	Rallyball	X			X
	River Rush	X			X
	Reflex Ridge	X	X		X
	Space Pop		X		X
	20,000 Leaks	X	X		X
Puss in Boots 	Market Mayhem	X	X		X
	Shape it up		X	X	X
	Bandit Boot			X	X
	Barrel Barrage		X	X	X
Tiger Woods PGA Tour 	Golfing	X	X		X

The intervention took 45 minutes to complete. During the allocated time five games were played by each participant and each participant's BP was measured five times using the Automatic Sphygmomanometer. During the 45-minute sessions there were five short breaks of two minutes between games that gave the participants a time to rest and for the new game to load.

Conventional physiotherapy (control) group intervention

The control group intervention was done in the seated, prone and supine positions. The control group treatment programme commenced with stretching of the muscles of the shoulder girdle and upper-limb and neural mobility of the brachial plexus. The intervention programme was based on the current treatment protocols in place at "Rehab Matters" and are described in Table 3.2 below.

Table 3.2 Summary of Control Group Intervention







Activity	Patient position / Apparatus used	Weighing / Resistance
<p>Stretching</p> 	<p>Seated. Manually.</p>	<p>At the beginning of the treatment session the muscles of participants' shoulders were stretched 3 x 30 seconds and their brachial neural tissue mobilised for 2 x 40 seconds.</p>
<p>Punching tasks</p> 	<p>Sitting. Wrist weights</p>	<p>Participants sat with their feet supported on the floor, as they punched a balloon that was suspended from the roof. The balloon was hanging at shoulder level and the patient was positioned so that the movement allows full elbow extension. The size of the weights was determined by the participant's ability to perform the activity bilaterally, 10 times before resting.</p>
<p>Muscle strengthening</p> 	<p>Dumbbell weights</p>	<p>Weight was determined by the participant's ability to perform 10 repetitions with the weight, before resting.</p>
	<p>Seated Proprioceptive Neuromuscular Facilitation (PNF)</p>	<p>Resistance was applied by the therapist allowing the participant to repeat the exercise 10 times before resting. Patterns used consisted of pattern 1: shoulder adduction, external rotation, flexion and pattern 2: shoulder abduction, internal rotation and extension</p>

Table 3.2(continued) Summary of Control Group Intervention

Activity	Patient position / Apparatus used	Weighing / Resistance
<p>Reaching tasks</p> 	<p>Both sitting and puppy position.</p> <p>Cones and washing pegs</p>	<p>Participants used standard rehabilitation cones and washing pegs as implements during the reaching tasks. They were required to pick up the objects and relocate them to the opposite limb's side.</p>
<p>Ball throwing</p> 	<p>Sitting and supine.</p> <p>Standard volleyball.</p>	<p>All participants threw the ball from both positions. In sitting, participants were expected to throw the ball in various directions while maintaining their balance. The participants were also required to catch the ball, when it was thrown to them. In supine the participants were expected to throw the ball up above their thoracic regions and catch the ball. This facilitated gross upper limb function and visual training.</p>
<p>Fine motor activities</p> 	<p>Board games with dice.</p> <p>Locks and keys (various sizes and shapes).</p> <p>Card games.</p> <p>Coin sorting.</p> <p>Pens / pencils holding and writing.</p> <p>Kitchen utensils (knives and forks).</p> <p>Clay.</p>	<p>Participants were in seated position for all the activities. A selection of two specific fine motor activities were performed in the treatment session and all the participants were exposed to all the different activities.</p>

The control group intervention also took 45 minutes to complete. During the allocated time all the activities listed in Table 3.2 were completed and the participants' BP was measured five times. During the 45-minute sessions there were five short breaks of two minutes between activities that gave the participants a time to rest.

3.7 Pilot Study

A pilot study was conducted after ethical approval was obtained from the University of Pretoria, Faculty of Healthsciences, Ethics Committee (Appendix H).

The objective of the pilot study was to replicate the proposed study on a small scale, so that an overview of the limitations of the study could be determined with regard to:

- time to complete demographic questionnaires, MMSE and consent forms;
- possible time restrictions
 - to determine whether 45 minutes was long enough for the different treatments; and
 - the time needed to complete the assessments;
- clarity of questionnaires, consent form and patient information leaflet;
- explanation and understanding of the VR apparatus – to determine critical markers to ensure safe and effective usage of VR apparatus;
- precision and reproducibility of the outcomes measures chosen.

Four participants who met the inclusion and exclusion criteria of the study were used to participate in the pilot study. The participants were people living in Bryanston who had been diagnosed with PD. Two participants received the VR therapy as a treatment modality and two the conventional physiotherapy group intervention. After the three assessments and twelve sessions of the intervention were completed the researcher and assessor were satisfied with the procedures followed and none of the anticipated limitations were experienced.

Therefore no changes to the methodology (processes and procedures) of the study were made and the results from the pilot study were included in the data analysis of the main study. The data captured during the pilot study were included in the final results, as no changes to the methodology occurred after the pilot study was conducted.

3.8 Data Management and Analysis

Data collected during the study was captured on the data capturing sheets (Appendix F [F1-3]) during the initial (baseline), mid-trial intervention and final assessments by the blinded assessor. Data collected from the 9HPT, TEMPA and King Devick Test was captured onto an Excel 2010 spreadsheet. Then the data was transferred into Stats12 format before final analysis was undertaken. Data collected from the demographic questionnaire was collected during the initial assessment only as it did not change throughout the course of the study.

All the quantitative data was analysed with MANOVA analysis because of the repeated nature of the data, adjusting for the initial reading, and taking into consideration of all the associated factors. None of the participants withdrew from the study at any time period.

Quantitative data analysis was conducted for the 9HPT, TEMPA and King Devick test. The King Devick test used a formula of age \pm the standard deviation (SD), to determine change. The SD for the King Devick test is 3.4. Results from the King Devick test had to improve with a minimum of 7 seconds to indicate a clinical and statistical significant change (kingdevicktest.com/for-concussions/). To ensure that there was a minimal clinical significant difference the scores of the 9HPT needed to improve with a percentage change of 54% (Earhard, Cavanaugh, Ellis, Ford, Froneman and Lee 2011:159). The data from the TEMPA was captured by measuring the time taken to complete the task. Analysis was done based on this time component.

3.9 Ethical Considerations

- Approval from the Ethics Committee of the Faculty of Health Sciences (University of Pretoria) was obtained before the pilot study and study commenced (Appendix H).
- The researcher signed and adhered to the ethical protocol as described in the Declaration of Helsinki (Appendix I).
- Permission to conduct the study at the “Rehab Matters” Rehabilitation Centre was requested from the practise owners (Appendix B).
- All people living with PD in the Bryanston area were asked to participate in the study on a voluntary basis. All participants were required to sign informed consent prior to participation in the study. The informed consent document describes the benefits and possible risks the participants might experience and clearly states the participants’ rights (Appendix C). Prior to the participants’ signing of the consent forms an information leaflet was given to each participant that explains what VR therapy is and how the study would be conducted.
- Confidentiality was maintained through-out the study as no names were recorded and participants were allocated numbers. This ensured anonymity of the research results.
- Participants could withdraw from the study at any stage and treatment would be discontinued.
- After completion of the study the collected data was stored in a secure location and will remain in this location for 15 years (Appendix G).
- There was no conflict of interest from the researcher and there was no financial remuneration from “Rehab Matters” or any other institute for the completion of the study.

3.10 Summary of Chapter 3

Chapter 3 described the methods used to execute the study. The participant recruitment and selection methods used for the study was described and the different intervention methods were set out.

The chapter also described the objective measures that were used during the data collection procedure as well as how the data was managed, after collection. All the

results from the objective measures were analysed by the statistician and the findings are set out in Chapter 4.

CHAPTER 4

RESULTS

4.1 Introduction

The aim of the study was to determine whether virtual reality (VR) therapy as a treatment modality is more effective than conventional physiotherapy for people living with PD. Upper-limb function and ocular tracking during IADLs and BADLs were examined and the results of the research are presented in this chapter.

The TEMPA outcome measure was used to determine the gross-, fine-, individual- and bilateral upper limb function. In order to get a comprehensive indication of fine hand movement the Nine-hole Peg Test (9HPT) was used as an additional measure of upper-limb function. Ocular tracking and the changes at baseline and after the intervention were measured with the King Devick test.

In Chapter 4 the results of the study are given. The results in this chapter includes the demographic data of the participants in each of the groups (experimental and control), as well as the results of each of the aforementioned objective measurements that were taken.

4.2 Demographic Information

Non-parametric testing measures were used for statistical comparison of the control- and experimental group at baseline (Meyer & Seaman, 2013:141). Results from the Kruskal-Wallis equality-of-populations rank test indicated that both groups were similar at baseline and comparable to each other with regard to the demographic information.

Participants in the study were between the ages of 52 and 75 years old. The average age for participants in the control and experimental groups is shown in Figure 4.1.

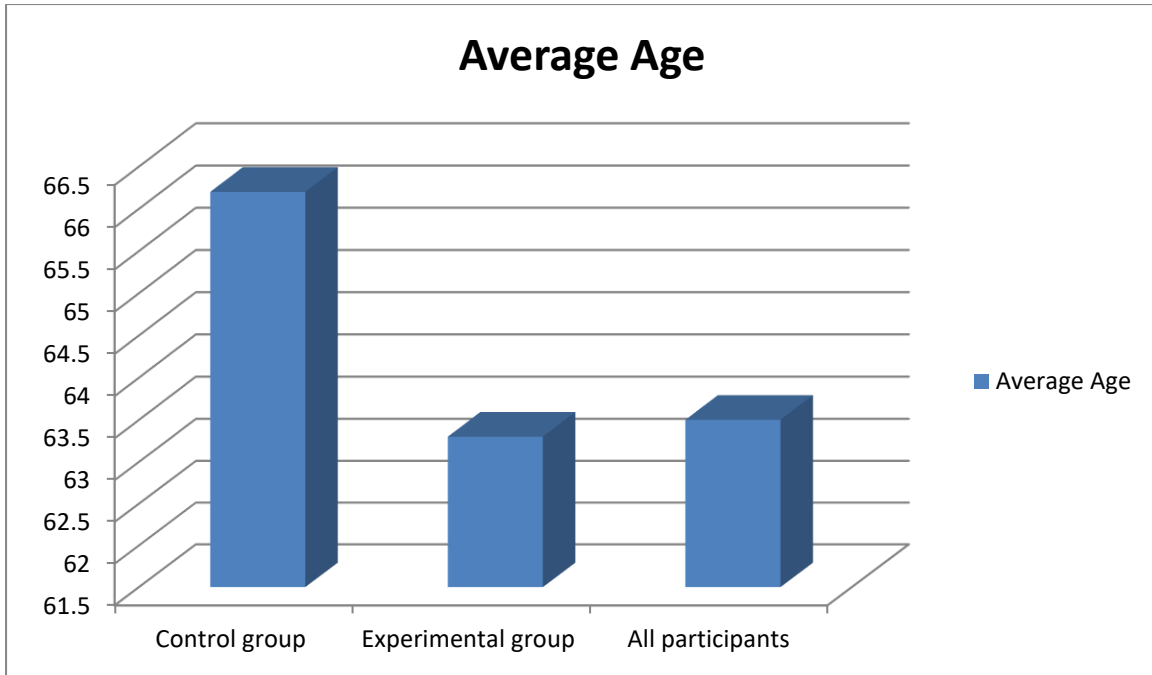


Figure 4.1 Average Age of Participants in the Control- and Experimental Groups

The average time since the onset of clinical signs and symptoms of PD was also calculated per group, and is shown in Figure 4.2.

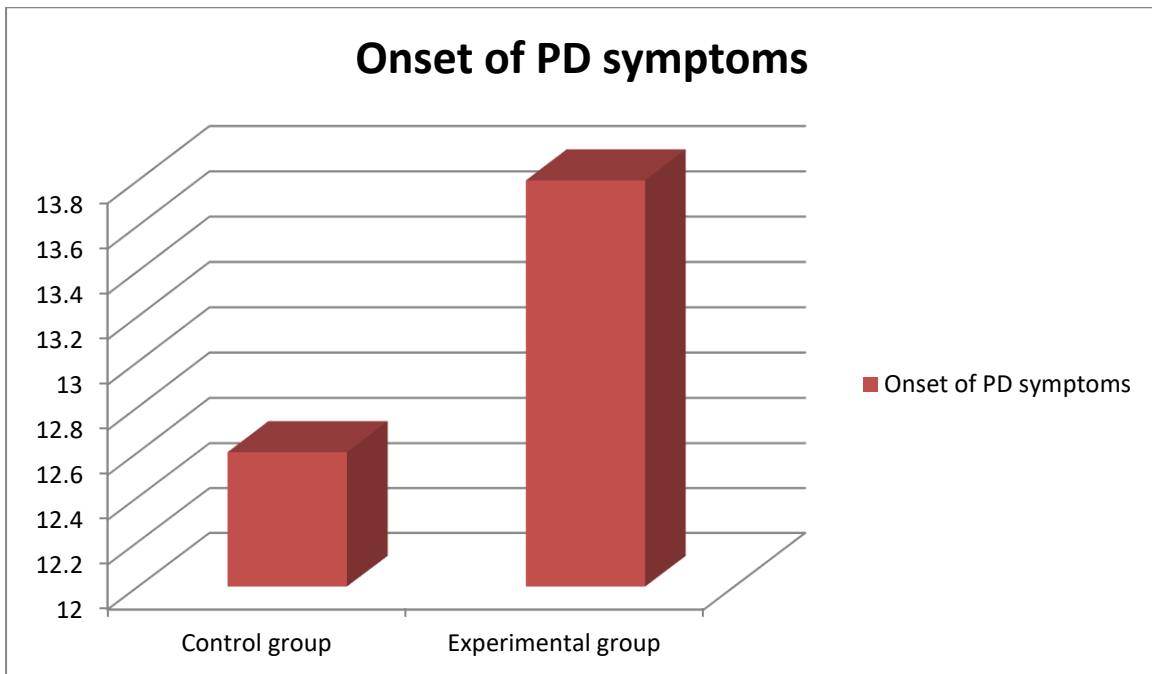


Figure 4.2 Average Years since Onset of PD Symptoms

Males and females of all races were included during the recruitment process. After randomisation, six male patients and five female patients were included in the control group and seven male patients and four female patients were in the experimental group. Fifteen Caucasian patients were included in the total sample of 22, of which eight were in the control group and seven were in the experimental group. Three African patients were included in the total sample, of whom two were in the control group and one in the experimental group. One Indian patient was included in the control group and three in the experimental group. Race and gender representations of participants in the study are shown in Figure 4.3 and Figure 4.4.

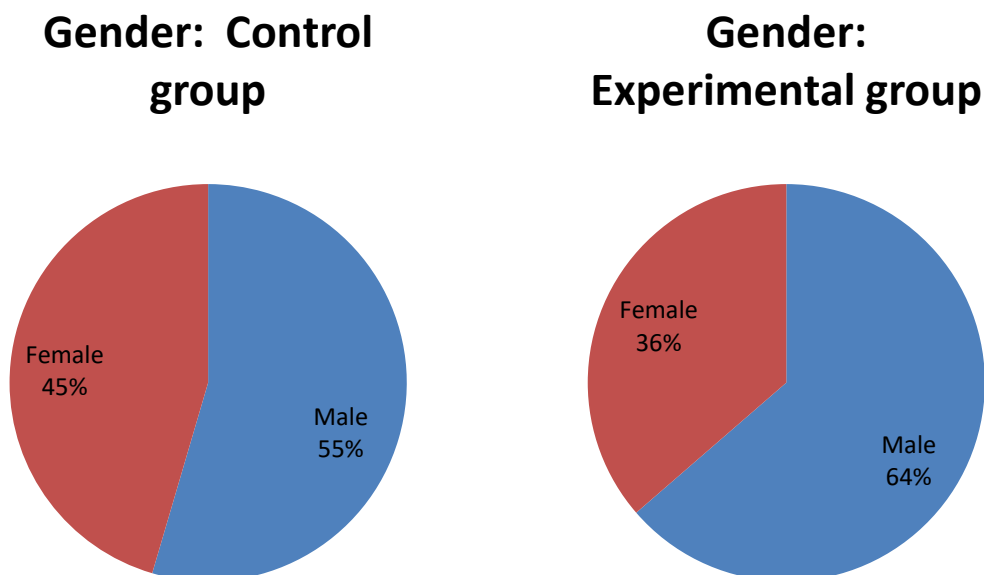


Figure 4.3 Gender Comparison between Control- and Experimental Group (n=22)

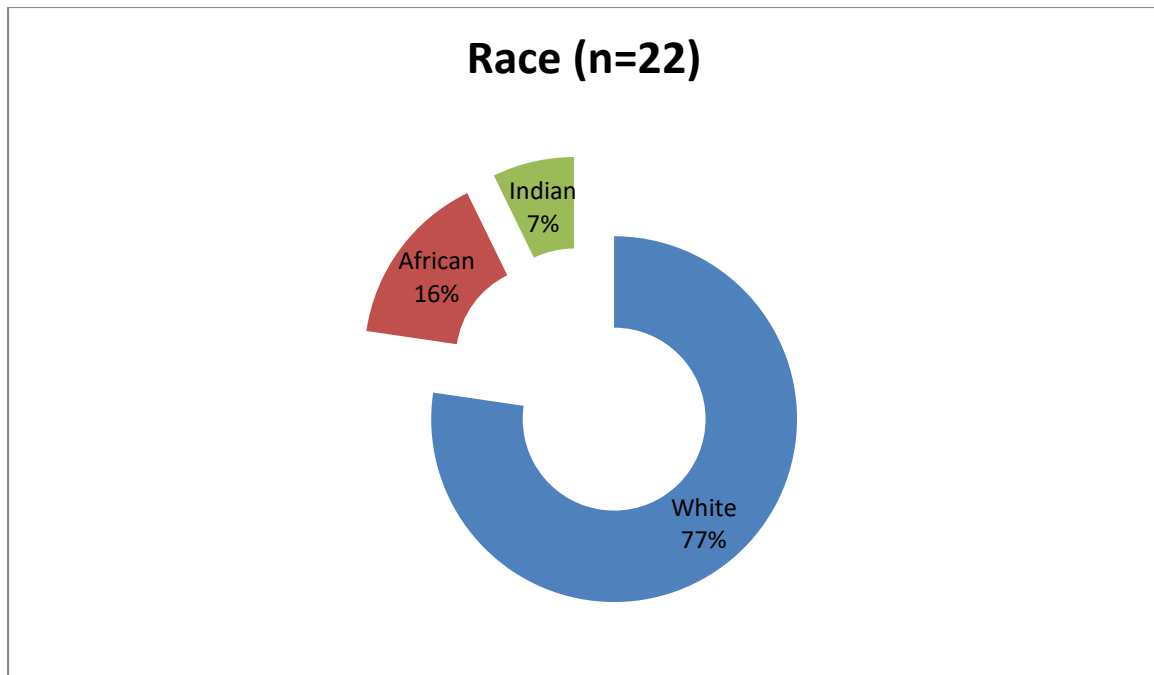


Figure 4.4 Racial Breakdown of Participants (n=22)

4.3 Results from the Outcome Measures

Each of the outcome measures that was used during the execution of the study is discussed separately, so that a clear and comprehensive conclusion can be made. This conclusion will be summarised at the end of Chapter 4.

4.3.1 Results from the TEMPA

The TEMPA is a comprehensive assessment tool that has the ability to indicate change in activity- and participation levels, as it includes functional tasks and tasks of IADLs and BADLs.

Four of the items on this eight-item tool assessed unilateral upper-limb function (for left and right upper limbs) and four of the items assessed bilateral upper-limb function. In order to gain a comprehensive perspective of the changes observed from baseline to post-intervention, each item was analysed and described separately. The total difference between the groups was compared and analysed and the analysis was presented at the the end of Section 4.3.1.

The first item on the TEMPA was a bilateral upper-limb task, where participants were asked to pick up a jar and move it using both hands. The time to complete the task was measured at baseline and post-intervention. Participants from the control group improved by 9.8 seconds, which does not indicate a clinically significant improvement from baseline (a change of 15 seconds for bilateral activities on the TEMPA indicates clinically significant change) (Feys, Duportail, Kos, Van Asch and Ketelaer 2002:168). Participants in the experimental group improved from baseline by 18.5 seconds, indicating clinically significant improvement. When the score for the task was compared between the two groups only a marginal statistical improvement was observed ($p=0.0611$).

The second item on the TEMPA is also a bilateral task, where participants were asked to open a jar and scoop out a spoonful of sugar. From baseline to final assessment, participants in the control group improved by 11 seconds, again, not achieving clinical significance. Participants from the experimental group improved by 27.4 seconds, which indicates a clinically significant improvement. When the two groups were compared, a statistically significant difference was observed between the control- and experimental groups ($p=0.0043$).

The third bilateral task was to pour water from a pitcher into a glass. Control-group participants improved from baseline to post-intervention assessment by 9.3 seconds and experimental-group participants improved by 27.1 seconds. Participants in the experimental group improved clinically significantly, but not the control group participants. The difference between the control and experimental groups were significant ($p=0.0078$).

The final bilateral task that was assessed with the TEMPA asked participants to open a lock and take the top off a pill box. Participants in the control group improved from 99.8 seconds at baseline to 94.1 seconds post-intervention, indicating that no significant change occurred. Participants in the experimental group improved from 144.5 seconds at baseline to 115.5 seconds post-intervention, indicating a clinically significant change.

The difference between the control- and experimental groups was also statistically significant, with the experimental group showing superior change in comparison to the control group ($p=0.0002$). Table 4.1 summarises the descriptive and non-parametric results for the TEMPA for bilateral activities.

Table 4.1 Summary of the Bilateral Upper-limb Non-parametric Results from the TEMPA Outcome Measure (seconds).

Item	Control Group			Experimental group			Difference between groups*
	Average time (baseline)	Average time (post-intervention)	Average difference	Average time (baseline)	Average time after (post-intervention)	Average difference	
Pick up and move a jar	88.2	78.4	9.8	102.4	83.9	18.5	0.0611
Open a jar and take a spoonful of sugar	97.7	86.7	11.5	129.8	102.4	27.4	0.0043*
Pour water from a pitcher into a glass	104.3	95	9.3	138.5	111.4	27.1	0.0078*
Open a lock and take the top off a pill box	99.8	94.09	5.7	144.5	115.5	29	0.0002*

*Indicates statistically significant change between groups at a confidence level of 95%.

Owing to the degree of significance that was achieved using non-parametric statistical analysis on the bilateral outcomes on the TEMPAs, parametric testing was also used to determine change from baseline to post-intervention for the control- and experimental groups. A two-sample t-test with unequal variances yielded the following results for the four bilateral tasks:

Results from task 1 (pick up a jar and move it) can be viewed in Table 4.2. Parametric analysis shows that the difference between the control and experimental group are not significant.

Table 4.2 Two-sample t-test with Unequal Variances for Task 1

Group	Observations	Mean	Std Err	Std Dev	95% Confidence interval	
Control	11	.171	.536	.178	.0515	.290
Experimental	11	.33	.078	.259	.156	.504
Difference		-.159	.948		-.357	.039
Difference = mean (control) – mean (experimental) H0: difference = 0 Welch's degrees of freedom = 19.2383 t = -1.6786 p=0.1094 (indicating non-significance)						

Parametric results from all three of the other tasks (i.e. open a jar and remove a spoonful of sugar; pour water from a pitcher into a glass; open a lock; and take the top off a pill box) showed significant results with parametric testing. Table 4.3, 4.4 and 4.5 illustrate the results from the parametric tests for tasks two, three and four.

Table 4.3 Two-sample t-test with Unequal Variances for Task 2

Group	Observations	Mean	Std Err	Std Dev	95% Confidence interval	
Control	11	.146	.063	.209	.006	.287
Experimental	11	.456	.073	.241	.294	.618
Difference		-.31	.096		-.510	-.109
Difference = mean (control) – mean (experimental) H0: difference = 0 Welch's degrees of freedom = 21.5423 t = -3.2172 p=0.0040 (indicating significance)						

Table 4.4 Two-sample t-test with Unequal Variances for Task 3

Group	Observations	Mean	Std Err	Std Dev	95% Confidence interval	
Control	11	.165	.069	.231	.009	.321
Experimental	11	.489091	.0572785	.1899713	.361466	.617
Difference		-.324	.090		-.512	-.136
Difference = mean (control) – mean (experimental) H0: difference = 0 Welch's degrees of freedom = 21.1025 t = -3.5800 p=0.0018 (indicating significance)						

Table 4.5 Two-sample t-test with Unequal Variances for Task 4

Group	Observations	Mean	Std Err	Std Dev	95% Confidence interval	
Control	11	.936	.052	.170	-.021	.208
Experimental	11	.58	.079	.262	.404	.756
Difference		-.486	.094		-.684	-.289

Difference = mean (control) – mean (experimental)
 H0: difference = 0
 Welch's degrees of freedom = 18.6307
 t = -5.1521
 p=0.0001 (indicating significance)

A summary of the difference in bilateral tasks between the control and experimental groups is illustrated in Figure 4.7.

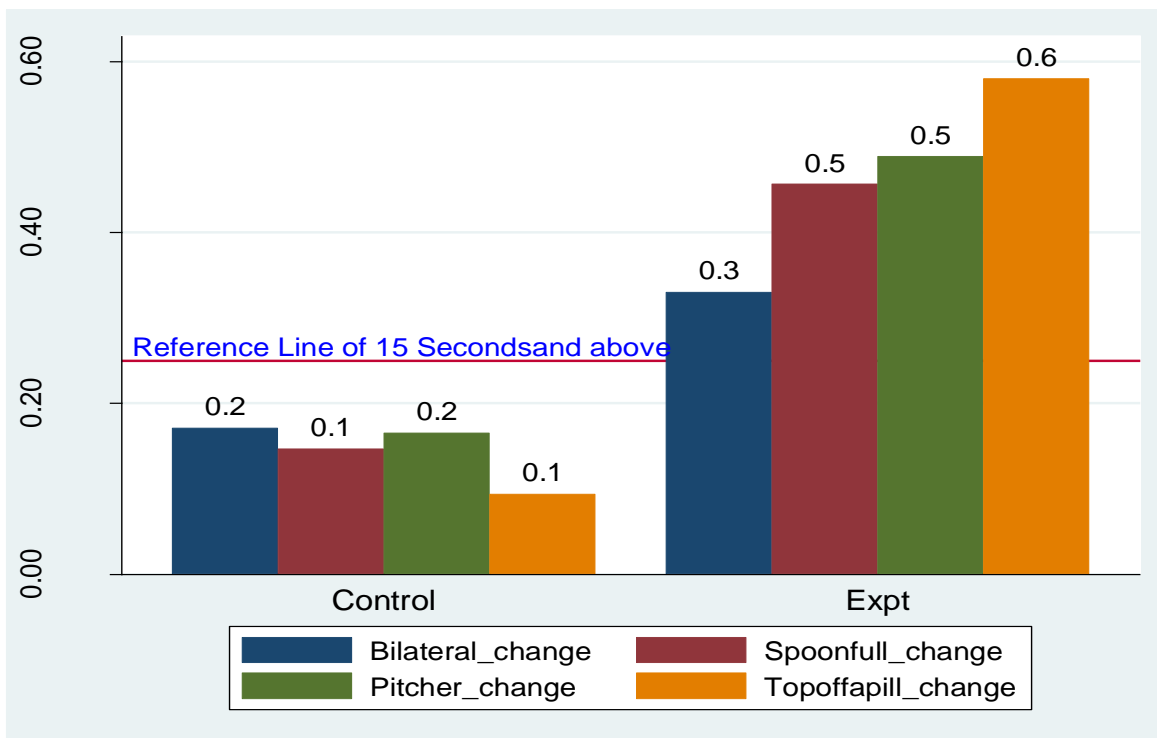


Figure 4.7 Summary of the Difference in Bilateral Tasks on the TEMPA

The results from Figure 4.7 show evidence that the treatment group improved significantly more in comparison to the control group with respect to the bilateral tasks.

In order to get an accurate indication whether there was a difference from baseline to post-intervention for the unilateral tasks, the right- and left upper limb for the control- and experimental groups were analysed separately. As the participants were affected bilaterally, dominance was not considered during analysis of the results. The unilateral tasks on the TEMPA were: (task 5) write and affix a postage stamp; (task 6) shuffle and deal cards; (task 7) use coins; and (task 8) pick up and move small objects. In order to determine clinically significant differences in improvement, participants needed to decrease the amount of time it takes to complete the task by at least 10 seconds (Feys, et al 2002:169).

Analysis of task 5, when performed with the left hand, showed that the control group improved from 69.8 seconds to 63.5 seconds (a 6.3-second change), while the experimental group improved from 115.6 seconds to 90 seconds (25.6 seconds). The experimental group, therefore, showed clinically significant improvement with the left hand during performance of task 5 of the TEMPA. Non-parametric statistical analysis also indicated that a statistically significant difference existed between the control- and experimental groups ($p=0.0115$). When the results of the completion of task 5 with the right hand were examined the control group showed a decrease of 18.3 seconds to complete the task, and the experimental group took 26.6 seconds less. Clinically and statistically significant differences between the two groups were established ($p=0.0151$).

Task 6 was also analysed with non-parametric statistics and the difference between the control- and experimental groups were non-significant for both the left- and the right upper limb (left upper-limb comparison: $p=0.4118$; right upper-limb comparison: $p=0.4306$). Although statistical significance could not be determined, the experimental group showed an improvement of 22.1 seconds when using the left hand to complete task 6 and an improvement of 22.7 seconds when using the right hand. The changes in both the left- and right hand are clinically significant.

Participants in the control group improved by 7.4 seconds in their completion of task 7 with the left hand and 15.5 seconds when completing the task with the right hand. The decrease in the amount of time it took to complete the task for the left hand did not indicate significant change, but the faster completion time of the right hand indicated clinical significance. Participants in the experimental group improved by 23.1 seconds when they used the left hand to complete task 7 and by 30.4 seconds when they completed the task with the right hand. Experimental-group participants showed clinically significant improvements for the left and right hand in performing task 7. Statistical analysis indicated that there was a statistically significant difference between the control and experimental group for the right hand when performing task 7 ($p=0.0064$). The analysis, however, revealed that there was not a statistically significant difference between the control and experimental groups when the left hand was compared ($p=0.2505$).

The final TEMPA task was to pick up an object and move it (task 8). Participants in the control group's time decreased by 9.4 seconds when they performed the task with the left hand and 9.2 seconds when performing the task with the right hand, again not showing any clinically significant change. Participants in the experimental group's times decreased by 24.7 seconds when they used the left hand and by 21.9 seconds when they used the right hand, indicating a clinically significant change. Non-parametric statistical analysis revealed statistically significant differences between the left- and right hand from baseline to post-intervention between the control and experimental group (left hand $p=0.0009$ and right hand $p=0.00114$).

As the results from the statistical analysis of the unilateral tasks were significant, further parametric analysis was performed. The results from the two-sample t-tests with unequal variances are presented in Figure 4.8. The left- and right hand comparisons were separated for a clear indication of significance achieved.

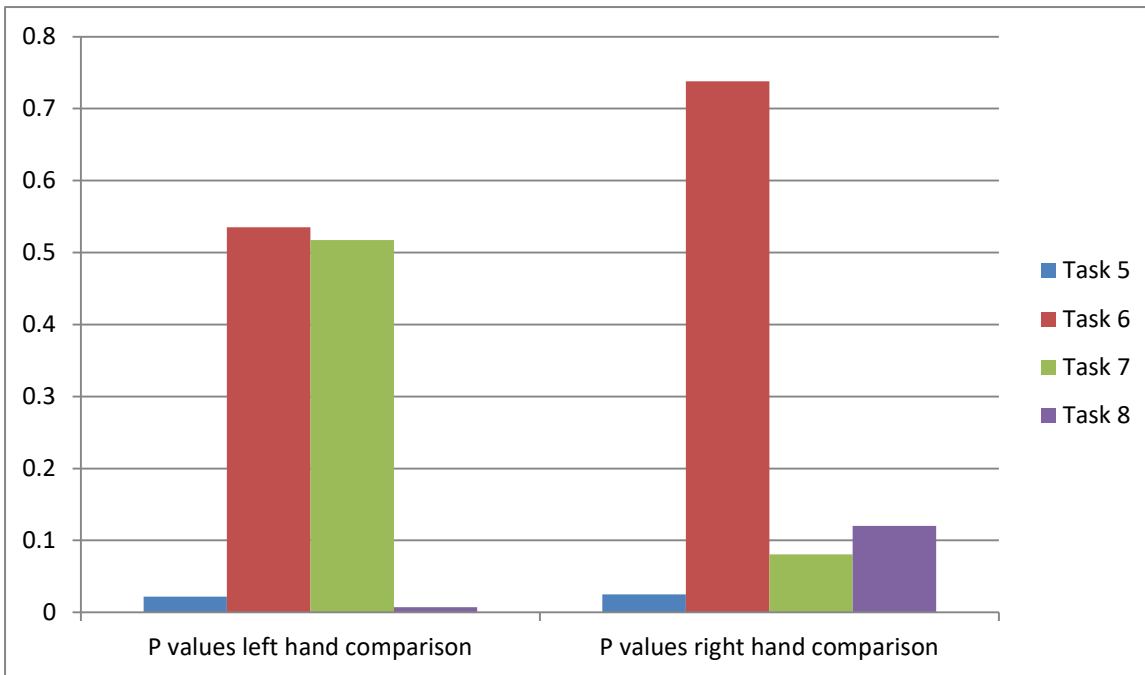


Figure 4.8 Two Sample t-test with Unequal Variances Analysis for Change from Baseline to Post-intervention for the Left- and Right Hands

The following statistically significant information can be seen in Figure 4.8. Task 5, when performed with the left hand, showed significant improvement for the experimental group, when compared to the control group ($p=0.0217$). When task 5 was performed with the right hand, statistically significant results were also found when the two groups were compared post-intervention ($p=0.0249$). Task 6, when completed with the left and right hands did not show a statistically significant change from baseline (left hand $p=0.5353$ and right hand $p=0.7381$). When the results from task 7 are analysed, no significant change between the control- and experimental groups were seen for the left or right hands (left hand $p=0.5175$ and right hand $p=0.0805$). The final task analysis (task 8) showed statistically significant change from baseline to post-intervention between the control- and experimental groups when the participants completed the task using the left hand ($p=0.0070$), but the analysis of the right-hand task performance did not show significant improvement ($p=0.1201$).

Figures 4.9 and 4.10 summarise the findings for the improvements between the control- and experimental group from baseline to post-intervention, using the TEMPA.

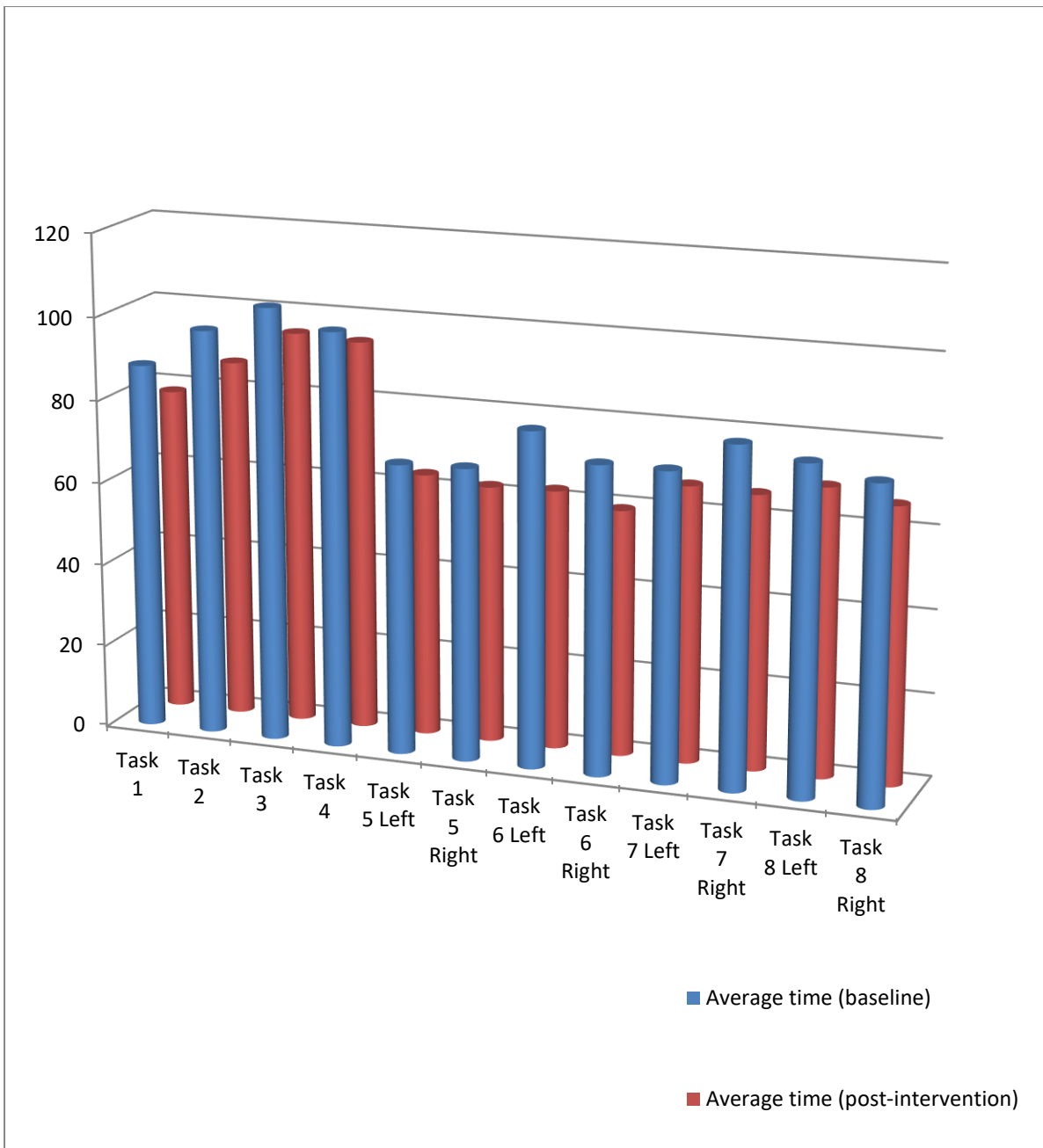


Figure 4.9 Average Difference in Times at Baseline and Post-intervention for the Control Group on the TEMPA.

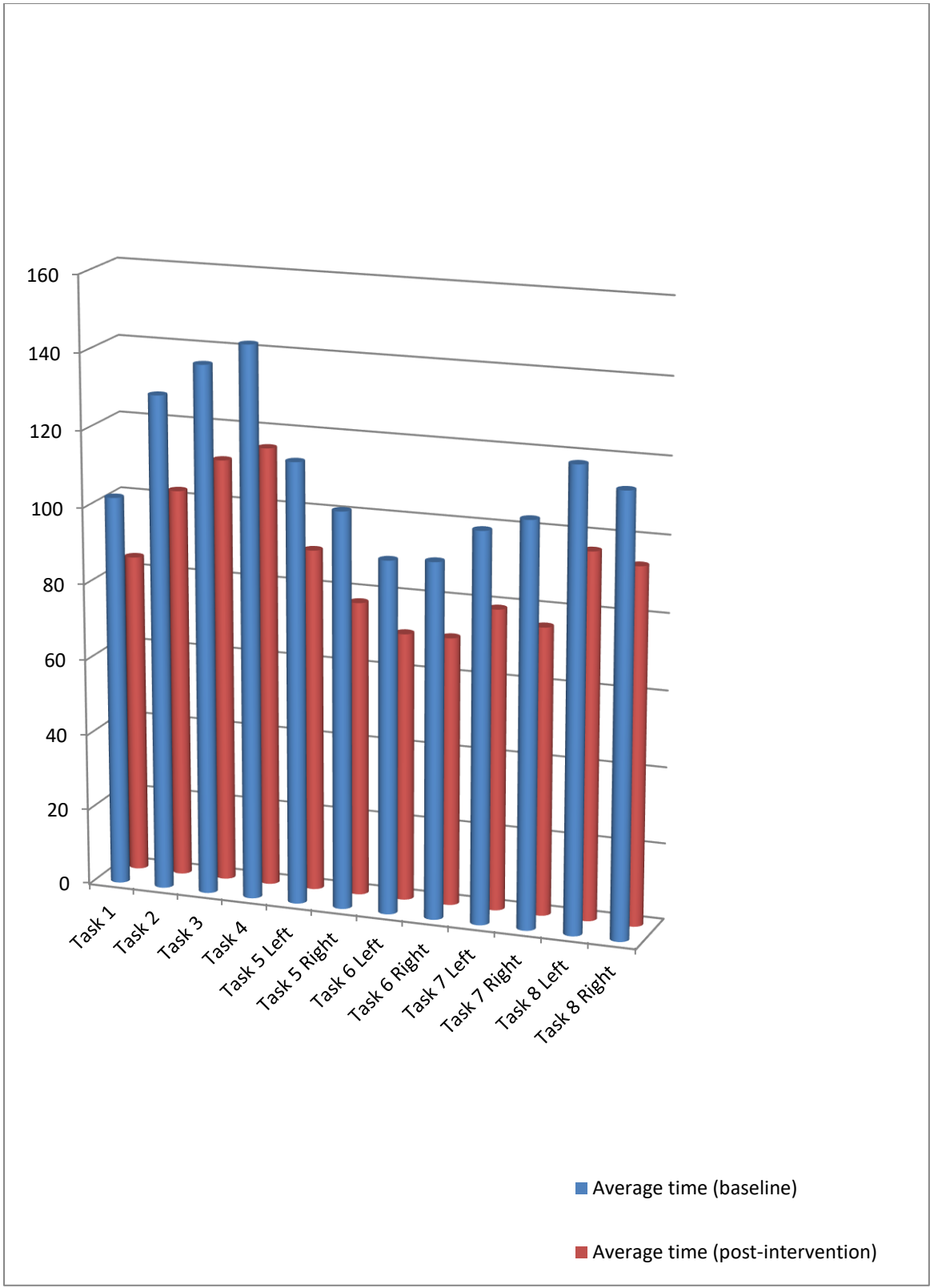


Figure 4.10 Average Difference in Times at Baseline and Post-intervention for the Experimental Group on the TEMPA.

4.3.2 Results from the 9HPT

The 9HPT was used in conjunction with the TEMPA to determine the effect of the intervention on fine hand function and coordination. The 9HPT is also a time based test and the results were determined at baseline and after twelve sessions of intervention. The results from the 9HPT are shown in Figure 4.11.

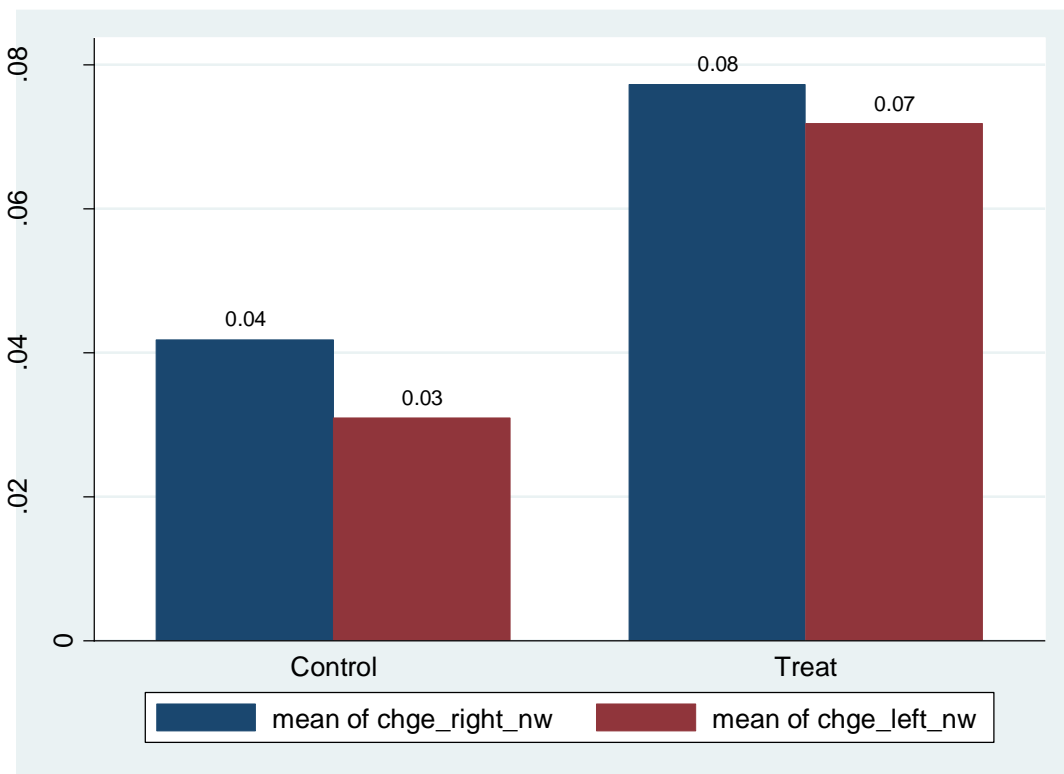


Figure 4.11 Difference between the Control- and Experimental Groups for the 9HPT

The results from the 9HPT for the left hand of the control- and experimental groups showed statistically significant improvements for both groups from baseline to post-intervention, but there was no statistically significant difference between the two groups. Similarly, changes for the right hand from baseline to post-intervention improved significantly for both the control- and experimental groups, but there was no statistically significant difference between the groups.

4.3.3 Results from the King Devick Test

The King Devick test examined eye movement and ocular tracking, by means of three separate yet similar tests. Participants had to read numbers from three pages and the arrangement of the numbers differed on each page.

The comparison of change between the two groups from baseline to post-intervention did not indicate clinically or statistically significant change (test 1 $p=0.0204$; test 2 $p=0.5320$ and test 3 $p=0.1608$). Three of the participants from the experimental group, however, showed clinically significant improvement from baseline. The results of the King Devick test are presented in Figure 4.12.

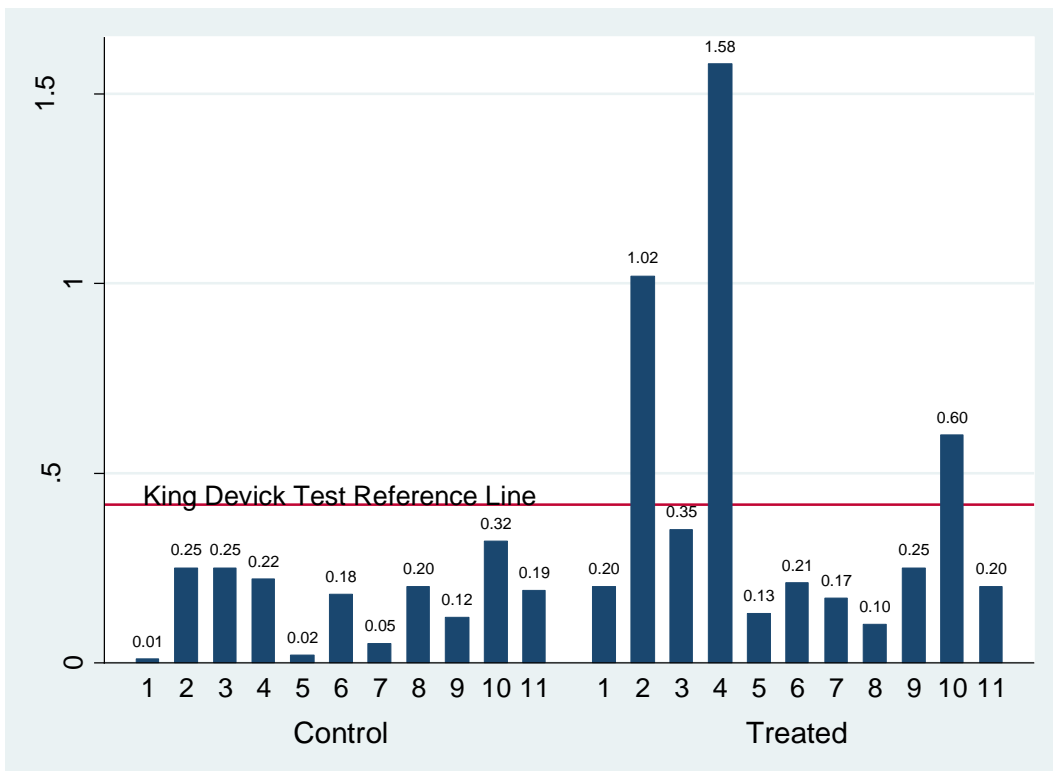


Figure 4.12 Comparison Between Participants on the King Devick Test.

4.4 Summary of Chapter 4

In Chapter 4 the results of the study were presented. These results that showed various clinical and statistical improvements between the two groups.

The results will be discussed at length in Chapter 5 and possible reasons for and clinical implementations of these results will be explored in the same chapter. Chapter 5 also contains the limitations of, recommendations from and conclusions of the study.

CHAPTER 5

DISCUSSION, RECOMMENDATIONS, LIMITATIONS AND CONCLUSION

5.1 Introduction

In Chapter 4 the results of the study was presented, both in text- and graphic format. In this Chapter the results are discussed in detail and the information from these results integrated to see whether the hypothesis of the study was accurate.

The aim of the study was to determine whether virtual reality (VR) therapy as a treatment modality is more effective than conventional physiotherapy in the rehabilitation of gross- and fine upper-limb movement, upper-limb function during IADLs and BADLs and ocular tracking in people living with Parkinson's Disease (PD). Chapter 5 also discusses the recommendations for further research, based on the findings of this study. The limitations that were experienced during the execution of the methodology and results analysis are also discussed.

5.2 Demographic Profile

The sample size of the study consisted of 22 participants which is generally accepted as a small sample size. However, when compared to incidence and prevalence studies conducted worldwide the number of participants is adequate. Despite the small sample size the participants were a true reflection of the population with PD in South Africa and therefore the results of the study are generalisable. The number of participants in this study correlates with other studies conducted in both developed and developing countries (Goodwin, et al 2008:635). In RCT studies that have been done on people living with PD the average sample sizes are between 11 and 56 participants, with a mean sample size of 25.6 (Goodwin, et al 2008:635). The sample size of this study is therefore in line with other PD research. The sample size was made up of a diverse mix of gender and race.

The gender comparison of participants in the study showed that there were slightly more males than females, but there was no significant difference between numbers of the genders.

This indicated that the study has a diverse representation (with regard to gender) and that the results may be generalised to all people living with PD in South Africa. The male-to-female ratio from this study correlated with prevalence studies done in both developed- and developing countries but it does not correlate to the previous prevalence study done in South Africa (Okubadejo, et al 2006:2154; Winter, et al 2010:352). The reason for this disparity might be that the previous prevalence study was done in 2006 and indicated only the number of people living with PD at that specific time. An incidence study may deliver more accurate results, but currently this information is not available.

The majority of the participants in the study were of the Caucasian race. The racial demographic of this study is in line with data from a study by Blanckenberg, et al (2013:23), who found that PD in the Sub-Saharan African population is more prevalent in the Caucasian race than the Black race. Although there were very few Indian participants in this study, the sample was inclusive of the three major racial groups in South Africa.

5.3 Discussion of the Results of the Outcome Measures in Terms of Patient Function

In order to determine the gross-, fine-, individual- and bilateral- upper-limb function the TEMPA outcome measure was used. The TEMPA is a comprehensive assessment tool that has the ability to indicate change on “activity” and “participation” levels (of the ICF), as it includes functional tasks and tasks of IADL and BADL. The aim of the study was to determine if VR therapy as a treatment modality was more effective than conventional physiotherapy in people living with PD with regard to upper-limb function and ocular tracking during IADLs and BADLs.

5.3.1 TEMPA: Bilateral Tasks

The first four items that the participants had to complete on the TEMPA were bilateral upper limb tasks. In the first task participants had to pick up a jar and move it using both hands. This task tested for both BADLs and IADLs and for picking up an object may be used in either basic or instrumental daily tasks. Participants from the experimental group showed clinically significant improvement from baseline to post-intervention, when compared to participants from the control group.

Clinical significant improvement indicates that the experimental group participants were able to perform the task faster and more accurately after the intervention than at baseline. The improvement also signifies that the participants were more functional, with regard to picking up jars, than they were prior to the VR therapy intervention – despite the task not being practiced specifically during the VR games. Participants in the control group also improved from baseline to post-intervention assessment, but the improvement was not clinically or statistically significant. When the outcomes of the task was compared between the two groups a statistically significant difference was not observed during parametric testing ($p=0.1094$). However, non-parametric statistical analysis reveal that the improvement showed a trend toward significance ($p=0.0611$). A bigger sample size or a longer intervention period may be indicated to get conclusive insight into the difference in improvement between the two groups.

The second item that the participants had to perform on the TEMPA was to open a jar and scoop out a spoonful of sugar. Participants from the experimental group improved by 27.4 seconds, which indicated a clinically significant improvement (from baseline to post-intervention). The execution of the task by the control group participants also improved from baseline to post-intervention (11.5 seconds), but the improvement was not clinically significant. The experimental group participants were thus able to perform this IADL task more competently and in less time after the intervention than at baseline. When the difference between the two groups are compared post-intervention, a statistically significant difference is observed ($p=0.0040$). This finding indicates that the experimental group benefitted from the VR therapy with regard to IADL function, more than the control group participants (who received the conventional therapy).

Task three was a BADL bilateral task, which required the participants to pour water from a pitcher to a glass. The experimental group's performance of the task improved clinically significantly from baseline to post-intervention (27.1 seconds). The participants in the control group also improved from baseline to post-intervention (9.3 seconds) but the improvement was not clinically significant. When the difference between the control- and experimental groups was compared post-intervention, the results were statistically significant ($p=0.0018$). These results indicated that VR therapy was more effective than conventional therapy in people living with PD with regards to upper limb function during bilateral BADLs.

The final bilateral task that was assessed with the TEMPA required participants to open a lock and take the top off a pill box as part of an IADL task. Participants in the experimental group again showed clinically significant improvement (29 seconds), and the control group participants improved, but not clinically significantly (5.7 seconds). The difference between the control- and experimental groups from baseline to post-intervention were also statistically significant ($p=0.0002$). The statistically significant improvement indicated that VR therapy was more effective than conventional therapy in people living with PD with regards to upper limb function during IADLs.

The findings from the bilateral IADL and BADL tasks are similar to those of the studies by Tarr, et al (2002:1090) and Golomb, et al (2010:6). The results from both these studies show that VR therapy improve motor control, and in this study, motor control of the upper-limb improved significantly when both hands were working together. Furthermore, the VR therapy allowed for repetitive practice of the functional activities, which aided the development of limb control and functional muscle strength development (Carr and Shepard 2013:43). Not only were the upper limb movements repeated, but the VR therapy allowed for task-oriented training to occur repetitively. Task-oriented training is known to aid neural plasticity and facilitate functional rehabilitation (Harvey 2009:252). Five of the six principles of task-oriented training (Harvey 2009:256-7) were implemented during the VR therapy, they were:

- **Specificity:** The tasks that were selected from the available games on the X-box[®] system specifically focused on bilateral upper-limb movements that are encountered on a daily basis. However, the exercises that were selected for the patients in the control group were also specifically selected to work on bilateral upper-limb function. The specificity of the tasks could therefore be the reason that both groups showed improvement from baseline to post-intervention. The significantly greater improvement that the experimental group achieved with regard to upper-limb function could be attributed to the combination of the task-oriented training principles that were applied during the VR intervention.
- **Mass practice:** The second principle of task-oriented training is mass practice. Mass practice entails the repetition of a specific task until the patient can master the task (Harvey 2009:256). Patients who successfully learn a task by using mass practice are more likely to achieve functional carry-over of the task (Coker 2004:190).

Although this study only measured the effect of the intervention directly after the intervention ceased, the carry-over from the virtual game play to the 'real-life' functional activities (as tested with the TEMPA) was significant. Further research to determine the long-term effect of the functional carry-over is therefore warranted.

- **Shaping:** Shaping occurs when the same task is repetitively practiced, but the task gets progressively more difficult to complete (Harvey 2009:256). Achieving shaping with PD patients in a non-virtual environment is generally difficult – as exercise progression is usually associated with increasing the weight of the object used during the task or increasing the speed at which the task is performed (Dibble, Hale, Marcus, Droge, Gerber and LaStayo 2006:1449; Goodwin, et al 2008:637-8). Patients with PD may not be able to tolerate the exercises if the weight of the object in the task is increased or when the speed of the task is increased. The VR games get progressively more difficult to complete as the patients progress through the different levels / stages of the games. The motivation to complete the different levels / stages (or to win the game) distracts the patients from the fact that the games are getting more difficult to complete (Chen, Kan, Chuang, Doong, Lee, Tsai, et al 2007:1152). Therefore, the VR therapy is able to get progressively more difficult without the tasks becoming impossible to complete.
- **Saliency:** The motivation that patients experience to successfully perform and complete tasks are referred to as 'saliency' (Harvey 2009:257). Studies have shown that VR therapy is more enjoyable than conventional therapy and patients are willing to practice for longer periods without rest, then when participating in conventional therapy (Laver, et al 2011:5; Lewis and Rosie 2012:1881). The VR therapy motivates the patients to achieve their goals more than conventional therapy, which might explain why the experimental group performed significantly better than the control group during the execution of the bilateral upper-limb tasks.
- **Knowledge of performance and results:** The final principle of task-oriented training that applied to the performance of bilateral upper-limb function is the knowledge of the results that the patients had immediately after completing the different games. Auditory feedback is frequently used in rehabilitation strategies to motivate patients to perform optimally, or to alert patients when the movement they are performing are not satisfactory (Carr, et al 2013:41).

The neurotransmitter that is responsible for a patient's ability to learn from auditory feedback is dopamine. In PD, the dopaminergic input to the striatum is impaired (and degenerating) resulting in patients experiencing difficulty learning through traditional feedback-mechanisms (Foerde, Braun, Higgins and Shohamy 2015:1067-8). Virtual reality therapy may provide the optimal means of providing feedback to patients, as the patients are immediately aware of their results (as soon as the game is over). Further research to investigate the association between VR therapy providing the knowledge of the results and the impact on the performance of the task is needed to corroborate this statement.

2.3.2 TEMPA: Unilateral Tasks

In order to get an accurate indication whether there was a difference from baseline to post-intervention for the unilateral tasks, the right- and left- upper-limb for the control- and experimental groups were analysed separately. As the participants were affected bilaterally, dominance was not considered during analysis of the results.

The first unilateral task of the TEMPA required the participants to write and to affix a postage stamp onto an envelope. Similar results were obtained for both the left- and right hands of participants in the experimental group for this task. The participants in the experimental group improved clinically significantly ($p=0.0115$ – left hand and $p=0.0151$ – right hand) when compared to the control group. The results from task 5 (the first unilateral task) indicate that the experimental group participants were able to perform the IADL task more accurately and faster than the control group, post-intervention.

The second unilateral task (task 6) required participants to shuffle and deal cards. Although statistical significance between results of the control- and experimental groups could not be determined post-intervention, the experimental group improved clinically significantly with the left and right hands (22.1 seconds – left hand; 22.7 seconds – right hand).. The control group also improved from baseline to post-intervention but the results were not clinically significant. These results indicate that the experimental group showed superior improvement with regard to the speed and accuracy of performing this fine upper-limb movement task.

The third unilateral task (task 7) required participants to pick-up and move coins. During this fine upper-limb movement task, the experimental group participants showed clinically significant improvement with the right hand from baseline to post-intervention (15.5 seconds). Performance of the task with the left hand did not improve clinically significantly for either the control- or the experimental group participants. The control group participants also did not improve clinically significantly with the right hand from baseline to post-intervention. When the performance of task 7 is compared between the control- and experimental group post-intervention a statistically significant difference was determined for the right hand ($p=0.0064$).

The final unilateral TEMPA task (task 8) entailed picking up an object and moving it. As with most of the TEMPA tasks, the participants in the experimental group improved clinically significantly from baseline to post-intervention (24.7 seconds - left hand; 21.9 seconds – right hand). Participants in the control group improved, but not clinically significantly. Comparison of the difference in results between the control- and experimental groups at post-intervention yielded statistically significant differences ($p=0.0009$ – left hand and $p=0.00114$ – right hand).

The underlying reasons for the change in performance for the unilateral TEMPA tasks that were observed in the control- and experimental groups are similar to the reasons for the improvement in the bilateral TEMPA tasks. The same task-oriented training principles (Harvey 2009:256-7) that were discussed in Section 4.3.1 apply, i.e.:

- The experimental group participants received specific exercises to improve fine upper-limb function. Not only were the VR-games selected to facilitate fine hand movement but the remote control that was used during the game play also required participants to use their hands more. The specific use of the remote during VR therapy can facilitate the development of fine hand movements and grip strength (Choi, Han, Kim, Kim, Im, Lee and Hyun 2014:490).
- Mass practice of the tasks were done similarly to Section 4.3.1. Participants in the experimental group were encouraged to practice for longer periods without rest than participants in the control group due to increased levels of motivation to complete or win each game (Pavao, Arnoni, De Oliveira and Rocha 2014:390).

- Shaping of each tasks occurred as the games that were selected during the VR therapy got progressively more difficult (the games that were added to the treatment regime progressed in terms of difficulty and each game progressed with regard to difficulty as the participants completed the different levels / stages of the games).
- Saliency and the knowledge of the results have been discussed in Section 4.3.1 and the same principles apply for the improved performance of the fine upper-limb tasks that were assessed with the TEMPA.

Another reason for the improved fine upper-limb function that was observed with the TEMPA was the inadvertent proprioceptive input that was provided when the participants were given the remote controls to play the VR games (Abbruzzese, Trompetto, Mori and Pelosin 2014:5). The proprioceptive input that the participants received with the remote can be classified as intrinsic, augmented feedback. This type of feedback does not rely on the dopaminergic pathways to distribute and process the input, which makes it an effective means for patients to receive input and feedback (Abbruzzese, et al 2014:6).

Although the majority of the results on the TEMPA showed favourable change for the experimental group, when compared to the control group, some of the tasks did not improve in either group. A reason for the discrepancy between the different tasks may be that the participants were not used to performing the tasks that were tested on a regular basis (Lang, Bland, Bailey, Schaefer and Birkenmeier 2013:107). If a task is practiced or performed regularly, the movement patterns that a patient use becomes set and the patient is able to perform the movement automatically (Carr, et al 2013:42). However, once the patient loses the ability to perform the movement greater effort is required to perform that movement. Tasks that were done on a regular basis prior to a movement disorder is easier to relearn after an injury was sustained – which might explain why the participants in this study struggled with the performance of the less commonly performed tasks (Carr, et al 2013:41-2; Lang, et al 2013:110).

The overall results of the TEMPAs support the hypothesis, which stated that: there would be a significant difference between the results of 12 sessions of VR therapy as a treatment modality when compared to 12 sessions of conventional physiotherapy with regard to gross- and fine upper-limb motor function during IADLs and BADLs in people living with PD. The TEMPAs were also one of the objective measures used to help answer the research question: What is the effect of VR training on gross and fine upper limb function and ocular tracking of individuals living with PD when compared to conventional physiotherapy?

The results from the TEMPAs also met the objectives that were set in Chapter 1, which were:

- That the quality of functional upper-limb movement before, during and after the intervention was determined by the Test TEMPAs;
- That VR therapy as a treatment modality is an effective in the rehabilitation of people living with PD; and
- That VR therapy is more effective than conventional physiotherapy with regard to retraining upper-limb function during IADLs and BADLs in people living with PD.

5.3.3 9HPT

In order to determine in-hand manipulation and fine upper-limb function the 9HPT outcome measure was used. The 9HPT evaluated whether VR therapy was more effective than conventional therapy in people living with PD with regards to upper-limb function during IADLs. The 9HPT was used in addition to the TEMPAs as it specifically assessed in-hand manipulation (which the TEMPAs do not address).

The results from the 9HPT for the left- and right hand of the control- and experimental groups showed clinically significant improvement (for both groups) from baseline to post-intervention. When the results of the difference between the groups at post-intervention was analysed no statistically significant difference was detected.

These results implicate that both groups were able to perform in-hand manipulation better than prior to intervention, but that none of the intervention methods were superior.

Once again, the lack of significant improvement between the groups could be attributed to the task that was required of the participants during the test. Manipulating pegs and placing them in holes on a square board is not a task that is performed on a daily basis. Tasks that are performed regularly are more likely to give a clear indication of the effectiveness of the intervention (Carr, et al 2013:41-2; Lang, et al 2013:110).

After the results of the 9HPT were analysed the research question was answered and the null hypothesis was found valid: There is no significant difference between the results of 12 sessions of VR therapy as a treatment modality when compared to 12 sessions of conventional physiotherapy with regard to fine upper-limb function during IADLs and BADLs in people living with PD. The 9HPT results therefore indicate that VR therapy is as effective as conventional therapy in the rehabilitation of fine upper-limb function and in-hand manipulation.

5.3.4 King Devick Test

The ability of participants to perform ocular tracking was measured with the King Devick test before and after the intervention. The comparison of change between the two groups from baseline to post-intervention did not indicate clinically significant or statistically significant change. This absence of change within the groups as well as between the groups indicated that the ocular tracking did not improve irrespective of the intervention that the participants received.

Although it was hypothesised that the screen onto which the VR game was projected was large enough to facilitate ocular tracking, the lack of change from baseline to post-intervention for the experimental group indicate that this was not the case. Similarly, the visual fields that were utilized during the conventional physiotherapy was not sufficient to allow for the retraining of ocular tracking. The results from this study also indicate that upper-limb function during the performance of IADLs and BADLs can improve, despite the lack of improvement in ocular tracking.

For the King Devick test, the null hypothesis was found valid, which stated that: There would be no significant difference between the results of 12 sessions of VR therapy as a treatment modality when compared to 12 sessions of conventional physiotherapy with regards to ocular tracking during IADLs and BADLs in people living with PD.

5.4 Limitations

The following limitations were experienced during the execution of this study:

- Although the objective measures that were selected during the study were carefully chosen to determine the objectives of the study, the 9HPT and the King Devick tests were not specific enough to measure change in the sample population. The task that is performed during the 9HPT assessment is not functional enough to measure task-oriented fine upper-limb movement. The test also did not measure the grip strengths of the participants in the study. The King Devick test has not been used extensively in PD research and might not be sensitive enough to measure changes in ocular tracking in this population.
- The sample size that was recruited for the study was sufficient to test the hypothesis, but the sample was too small to perform parametric statistical analysis on. A larger sample size might have provided a more substantial indication of the differences between conventional physiotherapy and VR therapy in the rehabilitation of PD patients.
- This study only aimed to test the short-term effect of VR therapy versus conventional physiotherapy. However, a study with a longer follow-up period might give a better indication of the carry over effect that was observed in this study.

5.5 Recommendations for Future Research

Several gaps in the literature and the execution of this study has been identified and the recommendation for future research are based on these gaps. The recommendations for future research are as follows:

- Conduction of a similar study with a larger sample size, greater recruitment area and longer follow-up period is warranted. The larger sample size, form a more representative population, will provide a clearer picture of the improvements that are possible when patients receive VR therapy. The 9HPT should also be replaced with a hand-held dynamometer to measure the changes in grip strength of the participants. The longer follow-up period will give a clear indication of the carry over effect that might be achieved with the VR therapy.
- The implementation of VR therapy as a home exercise programme should be researched, specifically to determine upper-limb function in patients with PD. The positive response from participants in this study with regard to the VR therapy indicate that the participants are more likely to continue VR therapy at home, than they are with conventionally prescribed physiotherapy home-based exercises.
- Different means of presenting the VR therapy to patients should could also be researched. This study utilized a television monitor and projector to display the picture on a screen. A study comparing the use of traditional television-based VR therapy to projected VR therapy (or VR therapy with a smartphone and tablet) may have significant effects on the fine in-hand manipulation of the patients, as the hand function required to operate the different systems will differ.

5.6 Conclusion

After the completion of this study the research question was answered and the results indicated that: VR training was more effective in the rehabilitation of gross- and fine upper-limb function than conventional physiotherapy for people with PD. This study also found that VR therapy and conventional physiotherapy does not improve ocular tracking in people living with PD. Despite the lack of improvement in ocular tracking, VR therapy is recommended for the rehabilitation of gross- and fine upper-limb function in people with PD.

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**APPENDIX A:
CONSORT Statement Checklist**



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	i
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	V
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	49
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	64
Participants	4a	Eligibility criteria for participants	54
	4b	Settings and locations where the data were collected	50
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	57
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	56
	6b	Any changes to trial outcomes after the trial commenced, with reasons	64
Sample size	7a	How sample size was determined	53
	7b	When applicable, explanation of any interim analyses and stopping guidelines	65
Randomisation:			49
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	49
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	49
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	49

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	49
	11b	If relevant, description of the similarity of interventions	57
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	65
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	65
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	71
	13b	For each group, losses and exclusions after randomisation, together with reasons	n.a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	71
	14b	Why the trial ended or was stopped	n.a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	72
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	71
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	83
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	83
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	84
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n.a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	96
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	97
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	97
Other information			
Registration	23	Registration number and name of trial registry	135
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	n.a

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



APPENDIX B:

Permission to Conduct Research at “Rehab Matters” Rehabilitation Centre

Permission to do the research study at this hospital and to access the information as requested is hereby approved.

January 2014

I, Amy Harrison, hereby give consent that Miss R Cochrane may use Rehab Matters for her Master's degree.

This letter serves to confirm that R Cochrane has been employed with McCulloch and Harrison Physiotherapists since 01 January 2012. We have also given our consent for her to conduct her Masters research at our facility.



Amy Harrison

Practice Owner

Practice number: 2009/010766/21



APPENDIX C:

Information Leaflet and Informed Consent Documentation

Dear Participant

Thank you for taking the time to read through this information leaflet. I am conducting a study to determine whether Virtual Reality therapy will benefit people living with Parkinson's Disease more than conventional physiotherapy, like the therapy you are receiving at the moment. This leaflet contains all the information you will need to decide whether you would like to be a part of my study. Should you have any questions when you are reading this leaflet, or after having read the leaflet, please feel free to ask me. If you decide to participate in the study, please sign the informed consent page (the last page of this document).

Title of the study:

Comparison of virtual reality therapy and conventional therapy on upper limb function and ocular tracking on individuals with Parkinson's disease: a single-blind randomised control study

General information about the study:

Parkinson's Disease is a degenerative condition that affects movement of the arm and hand and will impact on your ability to perform activities of daily living, such as grooming, writing, dressing and eating. People living with Parkinson's Disease need to remain active as long as possible to prolong the ability to care for themselves and ensure optimal quality of life. This study aims to compare conventional physiotherapy to virtual reality treatment with an X-Box Kinect® (video game). Virtual reality treatment is the use of a monitor and a console (e.g. X-Box Kinect®, Nintendo Wii®, Playstation®) that can be used to help movement and accomplish task specific strengthening. The study will determine whether virtual reality treatment of the shoulder, arm and hand is more effective than the current treatment regimens used by physiotherapists. The treatment will be done on an X-Box Kinect® to determine whether this videogame will help improve arm and hand function. If the X-Box Kinect® is effective it can be used during physiotherapy sessions and at home.

This study has been approved by the Ethics Committee of the University of Pretoria.

Benefits and significance of the study:

To determine if treatment with an X-Box Kinect® will improve gross and fine upper limb movement used during activities of daily living (e.g. dressing, grooming and eating) when compared to regular therapy.

This will provide therapists with new and more options when rehabilitating their patients. If the use of the X-Box Kinect[®] proves to be effective it may also be considered as a home exercise treatment modality.

What is the X-Box Kinect[®]:

The X-Box Kinect[®] is a video game with an avatar - a little man that imitates the movement you make. The gaming system works with a motion sensor that picks up everything you do, but it can also be controlled by means of a remote control. The entire treatment session will be done while you are seated. I will use a variety of pre-selected games that address both big and small upper limb movements. The games invariably include eye movement and scanning.

The treatments:

Treatments will be done at Rehab Matters Rehabilitation Centre in Rivonia, Johannesburg. If you agree to participate you will be asked to complete a MINI Mental Questionnaire to see if you are eligible to participate in the study. You will also be asked to complete a questionnaire with regards to your health and personal background before the treatment to help gather basic information that will be used when describing the results later on.

Everybody participating in this study will be randomly divided into two groups. The groups will receive different treatments but the same assessment. One of the groups will receive treatment with the virtual reality games. The other group will continue to receive their regular therapy. If you decide to sign the consent at the end of this document, you will be asked to choose a colour from an envelope – this will determine in which group you are.

Group 1 – Virtual Reality Therapy:

One therapist will conduct each session and all treatment will be done using the X-Box Kinect[®]. The first game for all participants will be Kinect Sport bowling beginner level. This is the easiest game and will allow you to get familiar with the X-Box Kinect[®]. The names of the games that will be used are: Kinect Sports; Kinect Adventures; Puss in Boots; Tiger Woods PGA Tour and Kinect Olympics. All games have four levels of difficulty. As you master a level, the difficulty will be increased to ensure the intervention stays challenging and interesting.

Group 2 – Regular Therapy

One therapist will conduct each session and will use conventional Physiotherapy treatment techniques (this is the current treatments in place for people living with Parkinson's Disease). The treatment regime will commence with upper limb stretching and neural mobility activities. The 12 sessions or eight weeks of treatment will consist of the following: upper limb isolated muscle strengthening, reaching tasks, ball throwing, punching tasks, peg board games and fine motor activities such as pins, in hand manipulation, writing and clay. Each activity will have three levels of difficulty to ensure the intervention stays challenging and interesting.

During the 45 minute sessions there will be short resting periods between activities. Your blood pressure and heart rate will be monitored throughout the session to ensure that you do not over exert yourself. The sessions must be completed over an eight week period. The initial, sixth and final treatment sessions will be 90 minutes of duration, as the arm function tests will have to be conducted as well as the normal treatment.

The assessment of eye movement, arm and hand function:

One physiotherapist will conduct all the assessments using all three tests each time. The 9Hole peg test consists of a nine by nine inch board with space for nine pegs to be placed in. All the pegs are equal in size and must be accurately placed into the holes in as little time as possible. The TEMPA is a test that looks at the quality of movement and time it takes to complete these movements. These movements are basic activities of daily living such as doing buttons and zips, making coffee and writing letters. Lastly the King Devick is an eye movement test to see how fast and accurate you can read a row of numbers spaced over a spread sheet.

Possible risks involved:

You may be photosensitive (sensitivity to flashing lights) to the images of the X-Box Kinect[®] and this may cause to epilepsy. If this is the case you will be withdrawn from the study. This does not mean that your rehabilitation will end, it only implies that the results from your assessments will not be included in the final writing-up of this study.

What will be expected from the participant?

Participants will be expected to attend and complete a 12 session treatment regime. No remuneration will be given to you as you are doing the study on volunteering basis. You will be contacted the day prior to treatment to be reminded of the treatment session. If you are unwell, please inform me or the rehabilitation centre one day prior to treatment. All sessions will be free of charge for the duration of the study.

Withdrawal from study:

If you want to withdraw from the study you may do so at any time. You will be asked to inform the researcher about your decision to withdraw prior to the session.

Disclaimer:

The practice owners of McCulloch and Harrison physiotherapists as well as the owner of Rehab Matters will not be held liable for any injury, damages or loss of personal belongings while attending sessions that forms part of the study.

Researcher: Rozelle Cochrane (072 312 5253)

Rehabilitation Practice: McCulloch and Harrison Physiotherapists Inc (011 803 6649)

Study Supervisor: Prof JM Mothabeng (082 956 5528)

Informed consent form

1 Title of research project: The effectivity of virtual reality training on upper limb function of individuals with Parkinson's Disease in comparison to conventional physiotherapy

2 I hereby voluntarily grant my permission for participation in the project as explained to me by

3 The nature, objective, possible safety and health implications have been explained to me and I understand them.

4 I understand my right to choose whether to participate in the project and that the information furnished will be handled confidentially. I am aware that the results of the investigation may be used for the purposes of publication.

6 Upon signature of this form, you will be provided with a copy.

Signed: _____ Date: _____

Witness: _____ Date: _____

Researcher: _____ Date: _____



APPENDIX D: Demographic Questionnaire



Demographic Data Capturing Sheets

Demographic Questionnaire:

Participants Number: _____

Today's Date: _____

Date of birth: _____

Onset of symptoms: _____

Gender: _____

Questions:

1. Ethnic origin (Check✓ only one):

White		Asian	
Black		Indian	
Hispanic		Other (please specify)	

2. Please indicate below which chronic condition(s) you have:

Heart disease	If yes, please specify	
	Please state whether on treatment or not: Yes No	
Lung disease	If yes, please specify	
	Please state whether on treatment or not: Yes No	
Blood sugar problems	Yes	No
Blood pressure problems	Yes	No
Epilepsy or fits	Yes	No
Other	Please specify	

3. In general, would you say your healthy is (Check✓ only one):


Excellent	
Very good	
Good	
Fair	
Poor	



APPENDIX E:

Mini Mental State Examination Outcome Measure

Picture 1 – Mini mental state examination (MMSE)

Temporal orientation (5 points)	What is the approximate time?
	What day of the week is it?
	What is the date today?
	What is the month?
	What is the year?
Spatial orientation (5 points)	Where are we now?
	What is this place?
	In what district are we or what is the address here?
	In which town are we?
	In which state are we?
Registration (3 points)	Repeat the following words: CAR, VASE, BRICK
Attention and calculation (5 points)	Subtract: $100-7 = 93-7 = 86-7 = 79-7 = 72-7 = 65$
Remote memory (3 points)	Can you remember the 3 words you have just said?
Naming 2 objects (2 points)	Watch and pen
REPEAT (1 point)	"NO IFS, ANDS OR BUTS"
Stage command (3 points)	"Take this piece of paper with your right hand, fold it in half, and put it on the floor"
Writing a complete sentence (1 point)	Write a sentence that makes sense
Reading and obey (1 point)	Close your eyes
Copy the diagram (1 point)	Copy two pentagons with an intersection 

Fonte: Brucki SMD, Nitrini R, Caramelli P, Bertolucci PHF, Okamoto IH. Sugestões para o uso do mini-exame do estado mental no Brasil. Arq Neuropsiquiatr. 2003; 61(3B):777-81.



APPENDIX F

Outcome Measures used during the Assessments

Appendix F 1: 9 Hole Peg Test

Attempt	Left Hand (seconds)	Right Hand (seconds)
1		
2		
Average		



Appendix F2: Test d'Evaluation des Membres Superieurs De Personnes Agees

Task	Left (time)	Right (time)
Pick up and move a jar		
Open a jar and take a spoonful of sugar		
Pour water from a pitcher into a glass		
Open a lock and take the top off a pillbox		
Write and affix a postage stamp		
Shuffle and deal cards		
Use coins		
Pick up and move small objects		

Appendix F3: King Devick Test:

King Devick	Answer Key Card i	Answer Key Card ii	Answer Key Card iii
	6-7-4-2-5	7-0-1-8-4	1-9-7-4-8
	6-0-5-7-9	8-2-0-7-9	8-6-4-2-7
	4-0-8-2-3	7-5-6-2-9	7-3-9-6-5
	5-3-6-8-7	8-4-3-6-1	2-9-3-7-2
	1-8-3-0-6	5-1-0-7-4	5-1-7-6-2
	3-1-4-8-5	1-3-0-2-6	9-4-0-2-8
	4-2-7-8-5	8-3-5-6-0	1-9-7-8-0
	3-7-4-8-1	0-7-5-6-7	3-8-5-3-6
Errors			
Time			
Total Errors			
Total Time			



APPENDIX G:

Data Storage

Principal Investigator declaration for the storage of research data and/or documents

I, the Principal Investigator Rozelle Cochrane
of the following trial/study titled: The effects of Virtual Reality training on gross and fine upper limb function when compared to conventional physiotherapy in individuals living with Parkinson's Disease
will be storing all the research data and/or documents referring to the above mentioned trial/study at the following address: University of Pretoria, Dr Savage Drive

I understand that the storage for the abovementioned data and/or documents must be maintained for a minimum of 15 years from the commencement of this trial/study.

START DATE OF TRIAL/STUDY: 1 January 2014

END DATE OF TRIAL/STUDY: 30 September 2016

UNTIL WHICH YEAR WILL DATA WILL BE STORED: 2031

Name: Rozelle Cochrane



Signature _____

Date 31 October 2016



APPENDIX H:

ETHICS APPROVAL



Ethics Approval

ETHICS REFERENCE NO. PROTOCOL NUMBER.	468/2013
PRINCIPAL INVESTIGATOR / STUDENT	Name & Surname: Ms R Cochrane Dept: Physiotherapy ; University of Pretoria. Cell: 0723125253 E-Mail: rozelle.cochrane@gmail.com
TITLE OF RESEARCH PROJECT	Comparison of Virtual Reality Therapy to Conventional therapy on upper limb function and Ocular Tracking on individuals with Parkinson's Disease: A single Blind Randomized Control Study



APPENDIX I:

Declaration of Helsink

RESEARCHER DECLARATION

Hereby I, Rozelle Cochrane in my capacity as head researcher, that

- 1 Research participants will be informed, information will be handled confidentially, research participants reserve the right to choose whether they want to participate and, where applicable, written permission will be obtained for the execution of the project.
- 2 No conflict of interests or financial benefit, whether for the researcher, company or organization, that could materially affect the outcome of the investigation or jeopardize the name of the University of Pretoria is foreseen.
- 3 Inspection of the experiments in loco may take place at any time by the committee or its proxy.
- 4 The information I furnish in the application is correct to the best of my knowledge and that I will abide by the stipulations of the committee as contained in the regulations.



5 Signed: _____

Date: 31 October 2016



APPENDIX J:

Letter of Statistical Support



BIostatISTICS UNIT

Private Bag X385, Pretoria, South Africa,
No. 1 Soutpansberg Road, Pretoria
Tel: 012 339 8519, Fax: 012 339 8582
URL://www.mrc.ac.za/

LETTER OF STATISTICAL SUPPORT

Date: 26/09/2013

This letter is to confirm that the student, **R. Cochrane**, a MPhysT student at Department Physiotherapy, University of Pretoria discussed the Project with the title **"THE EFFECTS OF VIRTUAL REALITY THERAPY ON GROSS AND FINE UPPER LIMB FUNCTION WHEN COMPARED TO CONVENTIONAL PHYSIOTHERAPY IN INDIVIDUALS LIVING WITH PARKINSON'S DISEASE"** with me. I hereby confirm that I am aware of the project and also undertake to assist with the statistical analysis of the data generated from the project.

DATA ANALYSIS

The objective is to determine whether VR therapy improves gross and fine upper limb function as well as upper limb activities while doing activities of daily living (ADL's) more than traditional physiotherapy in patients living with PD. Analysis will present descriptive summary. Furthermore, the analysis will evaluate the periodic changes between mid-term and initial, changes between final and mid-term changes and overall changes for each subject as well. The overall data will be evaluated using MANOVA because of the repeated data over the three time periods along with other demographic factors and the intervention which will be compared with the control. STATA 12.1 will be the package of choice.

SAMPLE SIZE

When the sample size in each group is 11, a two-group large-sample normal approximation test of proportions with a one-sided 0.050 significance level will have 85% power to reject the null hypothesis that the test and the standard are not equivalent (the difference in proportions, $p_T - p_S$, is 0.200 or farther from zero in the same direction) in favor of the alternative hypothesis that the proportions in the two groups are equivalent, assuming that the expected difference in proportions is 0.000 and the proportion in the standard group is 0.030.

Name Dr SAS Olorunju

Biostatistics Unit

MRC Pretoria

Tel: 0123398553

